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Comprehensive Breast Care in Women 40 to 70 Years of Age

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13. ABSTRACT (Maximum 200 Words) In 1999, we began a randomized study of 8 Family Practice residencies, to address previously documented inconsistencies regarding breast cancer screening and management of identified breast abnormalities. Residencies randomized to the intervention arm received a multi-component intervention addressing knowledge and management of breast cancer related issues and clinical breast exam (CBE) skills. Chart reminder systems included guidelines for appropriate follow-up of breast abnormalities. Physician's performance in clinical settings was assessed through chart audits for women 40 to 70 year old, for the pre- and post-intervention years. Physician's cognitive and clinical skills were assessed pre- and post-intervention, through knowledge test, CBE skills using live simulated models, and lump detection skills in silicone breast models. Results of the pre-intervention chart audit revealed screening rates for the 11 sites to range between 36%-61% for CBE, 27%-61% for mammography, and 13%-45% for both. Physician's performance on the knowledge test improved immediately following the workshop. Follow-up assessment one year later demonstrated improvement in pre-intervention scores, but decrease relative to scores immediately post-intervention. This was also true of the evaluations of CBE skills. Translatability of this project has already begun. The curriculum was revised for Nurse Practitioners and presented in five workshops during the Spring 2001.				
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FOREWORD

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In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

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5/31/01

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*Improved Follow-up of Breast Abnormalities Through
Comprehensive Breast Care in Women 40 to 70 Years of Age*

INTRODUCTION

I. SUBJECT OF GRANT

Improvement of primary care physician's skills at screening for breast cancer, detecting and following-up on breast abnormalities.

II. PURPOSE OF GRANT

This study is to address the problem of primary care physicians achieving sub-optimal levels of screening for breast cancer and sub-optimal levels of detection of breast lumps and follow-up of breast abnormalities for their female patients. The purpose of this study is to test a three-component intervention designed to enhance primary care physicians' skills in secondary prevention, diagnosis and follow-up of abnormal findings in the control of breast cancer. It is directed at the population of physicians (residents in training) in which a pilot study has shown sub-optimal management of breast problems. We are hoping to institutionalize a standard-based approach to breast cancer screening and management of abnormal findings, which should lead to the earliest diagnosis of breast cancer, which in turn will improve prognosis.

III. SCOPE OF RESEARCH

Since practicing physicians do not have access to techniques for primary prevention of breast cancer, this study is testing an innovative educational intervention designed to optimize secondary prevention, diagnosis and follow-up of abnormal findings. It is directed at a population of physicians (residents and faculty) in which a pilot study has shown sub-optimal management of breast problems. We will implement a standard-based approach to breast cancer screening and management of abnormal findings leading to earlier diagnosis of breast cancer and improved prognosis while simultaneously optimizing the current standard of care. Since this project is implemented in active practice settings of community based family practice residencies, this intervention should easily be translatable to practicing physicians as well as residency programs.

At the end of this study, our goal is to train family practice faculty from other family practice residencies to conduct our intervention, allowing it to be translated into their respective curricula and practices. Residents tend to carry their experiences from residency to their own private practice and future colleagues. The experience we will provide them will allow the various innovative elements of our intervention to be disseminated to their own and other private practice sites.

The technical objectives of the study are to:

Specific Aim 1: To determine the effect of a three-component intervention consisting of: 1) Educational material on comprehensive breast care; 2) CBE Skills Course; and 3) Chart Reminder/Guideline System (CRGS) on rates of CBE and mammography, documentation of findings, and timeliness and appropriateness of follow-up of abnormal findings.

Hypothesis 1: When compared with the control sites, where no significant change from Year 1 to Year 2 is expected, practices receiving the intervention will demonstrate a significant increase in rates from baseline to post intervention, for breast cancer screening, follow-up of breast abnormalities and compliance with guidelines as expressed by an:

- a) increase in proportion of eligible women receiving the combined screening modality of CBE and mammography, from the current rate of 35% to 60%;
- b) increase in adequate documentation of findings from CBE on the breast history/exam form; the baseline rate of documentation will be established at pre-intervention chart audit;
- c) increase in documentation of findings from the mammogram, of subsequent follow-up and results obtained, from the current level of 30% to at least 70%;
- d) decrease in the mean length of time from the identification of the abnormality to the appropriate follow-up step as defined by the protocol; the baseline mean length of time to follow-up will be established at pre-intervention audit;
- e) increase among patients with abnormalities of the proportion in whom proper follow-up occurs by 3 months, from the current estimated 75% to 95%;
- f) increase in the level of appropriate follow-up as measured by percent of abnormalities that were followed according to the protocols provided in the guidelines (**Appendix4**); baseline levels will need to be assessed at the time of initial audit.

Specific Aim 2: To determine the immediate effect of:

- 1) Educational Session on knowledge, attitudes and beliefs about breast cancer screening, early detection and follow-up of abnormalities detected; and
- 2) Clinical Skills Course on the confidence and competence with which family practice physicians and residents perform CBE.

Hypothesis 2: As a result of the training sessions, we will observe immediate

- a) increase in post-session scores compared to pre-test scores on: knowledge, attitudes and beliefs about breast cancer screening and early detection;
- b) increase in the percentage of lumps detected from an expected baseline of 40% to 60% immediately post-training;
- c) increase in the proportion of the correctly conducted components of the CBE technique from baseline.

The baseline proportion will be established at the pre-training evaluation.

Specific Aim 3: To describe the long term effect of:

- 1) Educational Session on knowledge, attitudes and beliefs about breast cancer screening, early detection and follow-up of abnormalities detected; and Clinical Skills Course on the confidence and competence with which family practice physicians and residents perform CBE.

***Improved Follow-up of Breast Abnormalities Through
Comprehensive Breast Care in Women 40 to 70 Years of Age***

BODY

I. STATEMENT OF WORK

The following table outlines the tasks and timeframe as described in the original proposal. We have added the actual time (when the task was actually completed) and current status for a quick review of our progress. Text following the table describes the details of the task. ***All tasks that were completed during Year2 are in italics and bolded in the table below.*** For tasks that were performed during both years, the detailed description of each task that follows this table indicates which parts were performed in Year1 and which in Year2.

Task	Proposed Time Frame	Actual Time Frame	Status
Task 1. Develop, pilot test and refine chart audit and fact/documentation forms.	March – May, 1999	March – June, 1999	Completed
Task 2. Develop materials on risk management principles and guidelines for follow-up of abnormal findings for the Educational Session course pack.	March-June 1999	March-June '99	Completed
Task 3. Preparation of sites • <i>Each residency site generates a list of female patients 40 to 70 years of age</i> • Randomize residency sites to intervention and control arms	March-April 1999 (Year1)	March – July, 1999 (Year1) <i>August 2000, (Year2)</i>	Completed <i>Completed</i>
		March, 1999	Completed
Task 4. Assemble Chart Reminder/Guideline kits for all patients identified in Task 3 for the intervention sites.	May-June 1999	July – August, 1999	Completed
Task 5. Train nurse abstractors • Hire 2 nurse abstractors at each site (8 sites). • Bring all 16 nurse abstractors to MSU for a two day training workshop. • Distribute to the nurse abstractors the required number of chart audit forms and CRGS kits to be inserted at the time of the audit into the charts of all age eligible women.	June 1999	August, 1999	Completed
Task 6. Develop data management system for chart audit data • <i>Adjustments to the database for Year2 abstracting</i>	June-July1999	July - September 1999	Completed
		<i>September-October 2000</i>	<i>Completed</i>

Task	Proposed Time Frame	Actual Time Frame	Status
Task 7. Training of evaluators for workshop (month 4) <ul style="list-style-type: none"> hire and train patient instructors in evaluation of clinical breast examination technique train faculty in evaluation of clinical breast examination technique 	June 1999	June - July 1999	Completed
Task 8. <i>Workshop on 'Screening and Diagnosis of Breast Cancer for Primary Care Physicians'.</i> <ul style="list-style-type: none"> <i>Collect baseline data on knowledge, attitudes, and beliefs about breast cancer screening and early diagnosis using the 'Knowledge, Attitudes and Beliefs' Survey developed and used by Costanza.</i> <i>Collect baseline data on skills in CBE performance.</i> <i>Conduct the one day Workshop consisting of the Educational Session and Clinical Skill Course.</i> <i>Repeat all measurements from the pre-test at the end of the Workshop.</i> 	Intervention Sites (Year1) July 1999 Control Sites (Year2) August – September 2000	July-August 1999 (Year1) August 2000 – January 2001	Completed Completed
Task 9. <i>Data entry and analysis of data collected at time of intervention:</i> <ul style="list-style-type: none"> <i>pre-post outcome measures on knowledge, attitudes, and beliefs about breast cancer screening and early diagnosis;</i> <i>pre-post outcome measures on CBE skills</i> 	Intervention Sites (Year1) July-August 1999 Control Sites (Year2) September – November 2000	December 1999 – January 2000 (Year1) January – March 2001	Completed Completed
Task 10. Baseline chart audit (for the baseline year 8/1/98-7/31/99)	July -Sept 1999	September 1999 – April 2000	Completed
Task 11. Quality control assessments of baseline chart audits at each practice site	July and August 1999	October – December 1999	Completed
Task 12. <i>Data entry and analysis of baseline chart audit:</i> <ul style="list-style-type: none"> <i>Data entry</i> 	July-December, 1999	September 1999 – February 2000 (Year1)	Data entry completed at time of chart audit. Data entered directly on laptop.
<ul style="list-style-type: none"> <i>Data analysis of baseline outcome measures</i> 	December, 1999 – June, 2000	March 2000 – February 2002.	In progress

Task	Proposed Time Frame	Actual Time Frame	Status
Task 13. Assessment of retention of training effect <ul style="list-style-type: none"> • Train evaluators <ul style="list-style-type: none"> • hire and train patient instructors in evaluation of clinical breast examination technique • train faculty in evaluation of clinical breast examination technique • Collect follow up data on knowledge, attitudes, and beliefs about breast cancer screening and early diagnosis using the 'Knowledge, Attitudes and Beliefs' Survey developed and used by Costanza. • Re-evaluate skills in CBE performance • Repeat all measurements from the original pre-test 	Train evaluators - May, 2000 Collect follow-up data and re-evaluate skills – June, 2000	April, 2000 May and June, 2000	Completed
Task 14. Data entry and analysis of data collected for the evaluation of training retention <ul style="list-style-type: none"> • data entry of outcome measures on knowledge, attitudes, and beliefs about breast cancer screening and early diagnosis • data entry of outcome measures on CBE skills • data analysis of knowledge, attitudes and beliefs about breast cancer screening and early diagnosis • data analysis of outcome measures on CBE skills • compare data from Task 16 (retention of training effect) to data from Task 8 (pre-training and immediate post-training) 	July – August, 2000	July 2000 – February 2001	Data Entry and Analysis Completed
Task 15. Assess implementation of CRGS <ul style="list-style-type: none"> • convene focus groups at each site • identify local implementation issues • identify global implementation issues • compare and contrast themes across sites 	June, 2000	May and June, 2000	Completed
Task 16. Hire and train nurse auditors for the post-intervention chart audit.	May-June, 2000	September, October, 2000 and January, 2001	Completed
Task 17. Post-intervention chart audit (8/1/99-7/31/2000)	July- Sept, 2000	November, 2000 – April 2001	In progress
Task 18. Quality control of the post-intervention chart audit at each practice site.	July-August, 2000	December 2000 –February 2001	Completed

Task	Proposed Time Frame	Actual Time Frame	Status
Task 19. Data entry and analysis of the post-intervention chart audit <ul style="list-style-type: none"> • data entry • data analysis of pre-post intervention changes in the outcome measures defined in hypotheses 1a-1f 	July – October, 2000	November, 2000 – May 2001 May 2001- February 2002	Data entry occurs at the time of chart audit. Data analysis in progress
Task 20. Manuscript preparation.	August 2000- February, 2001	Nov.2000 through February 2002	In progress

II. WORK ACCOMPLISHED

For each task we will specify when it was performed, i.e. Year1 only, Year2 only, or Year1 and Year2. If Year1 only is specified the description of that task does not differ from the one provided in "Year One Annual Report."

TASK 1(Year1 only): Develop, pilot test and refine chart audit and fact/documentation forms.

No change from Year One Annual Report.

The chart review form originally submitted for the grant was developed by Drs. Janet Osuch M.D. and Dorothy Pathak, Ph.D., specifically for that purpose with the understanding that it would need to be peer-reviewed and field tested. The research team spent many sessions revising the form and it was then tested on a number of charts and modified further. The research team decided that given the complexity of the information that needed to be abstracted, it was more efficient to develop a chart-audit form where data could be entered directly onto a laptop computer. A detailed description of the development of the chart audit form/database is provided in the description of **Task 6**. Feedback from the nurse abstractors was incorporated into the final version of the abstracting form/database. A hard copy of the chart audit form/database can be found in **Appendix 1**. Data were entered on this form via direct computer entry.

TASK 2(Year1 only): Develop materials on risk management principles and guidelines for follow-up of abnormal findings for the Educational Session course pack.

No change from Year One Annual Report.

This task was accomplished in concert with a major curriculum revision. It was originally intended that the breast care curriculum written by Janet Rose Osuch, MD for the American Medical Women's Association be used. This curriculum, first published in 1994, had been revised and expanded twice since originally written. It was decided that another major revision was necessary to accomplish the goals of the grant and to design the optimal learning experience for the participants. This was accomplished during the summer of 1999. A copy of the final curriculum, which included 256 images, can be found in **Appendix 2**. It incorporates principles of risk management into the didactic elements of the curriculum.

To illuminate the importance of these principles, additional elements of the curriculum were added. Developed by Drs. Osuch and Pathak, they serve as summaries in the form of tables and algorithms for each category of screening depending on risk and for work-up of each of the breast abnormalities. They can be found in Appendices 1, 3, 4, 5a, 5b, 5c, 6, and 7 of the curriculum manual (**Appendix 2**). A summary of common allegations for failure to diagnose breast cancer, included recommendations for risk management, that were published in an article by Osuch and Bonham in Cancer in 1994. This was revised by Dr. Osuch for purposes of the grant and can be found in Appendix 9 of the curriculum manual. Guidelines on what attorneys expect from a chart that has been properly documented had been published on-line at the web site Medscape by Osuch and Bonham in 1998. This was summarized by Dr. Pathak for inclusion in the curriculum and can be found as **Appendix 3** of this Year2 Annual Report..

TASK 3(Year1 and Year2): Preparation of sites.

- Each residency site generates a list of female patients 40 to 70 years of age (Year1 and Year2);
- Randomize residency sites to intervention and control arms (Year1 only).

List of female patients 40 to 70 years of age (Year1 and Year2).

In Year1, Dr. Jodi Holtrop, Project Manager contacted each of the residency program directors for the name and the number of a contact person for each site. This person was either the nurse manager or practice manager. Dr. Holtrop arranged an initial meeting with the contact person at each site. During the meetings, Dr. Holtrop introduced the site contact person to the overall plan and process for the study. The tasks that needed to be accomplished at each site **during Year1 and Year2** are outlined below:

1. Determination of patients eligible for the study. Site contacts were to generate a list of patients who met the following criteria for inclusion in the study:
 - Female
 - Active patients in the practice. This was defined as having at least one visit in the past three years (or since 8/1/96).
 - Between the ages of 40-70, i.e. born after August 1, 1928 and before July 31, 1959 for Year1 and between August 1, 1928 and July 31, 1960 for Year2.
2. Orientation and assistance of nurse abstractors to be working at the site. The list of generated names was provided to the nurse abstractors at their orientation session at the residency program site. The initial orientation meetings were held in August of 1999 for Year1 and in September/October 2000 for Year2.
3. In Year1, the Chart Reminder Guideline System was inserted into the records of eligible patients at Intervention sites only. The organization of charts at each site was reviewed. The contact person and Dr. Holtrop agreed on what would be the best place in the chart at each site, for insertion of the Chart Reminder Guideline System (described in Task 4).

In Year2, the "Guidelines" and the "Summary Sheet of Breast Care Activity" sheets that were inserted during Year1 were stamped to indicate that they were a part of a research project.

No change from Year One Annual Report.**Randomize residency sites to intervention and control arms (Year1 only).**

Dr. Dorothy Pathak completed a random assignment of sites to the intervention and control arms. The Grand Rapids Family Practice Residency site could not participate in this project as in the meantime they have agreed to participate in a breast cancer screening project that was funded prior to this grant. Consequently we have solicited participation of Providence Hospital in Southfield, Michigan which the research team felt would resemble the patient characteristics of the population in Grand Rapids. Dr. Dickson, Research Director of the family practice residency program at Providence Hospital was very interested in participating in this intervention trial and agreed to take part. The following sites were designated as Intervention and Control. The residency program sites were notified of their intervention or control status at the April, 1999 meeting of Residency Program Directors for the MSU Network.

Intervention:

Kalamazoo Center for Medical Studies
 MidMichigan Regional Medical Center - Midland
 Saginaw Cooperative Hospitals, Inc.
 Sparrow/MSU

Control:

Genesys Health Systems, Flint
 McLaren Regional Medical Center, Flint
 Munson Medical Center, Traverse City
 Providence Hospital, Southfield

TASK 4(Year1 only): Assemble Chart Reminder/Guideline kits for all patients identified in Task 3 for the intervention sites.

The Chart Reminder Guideline System (CRGS) consisted of three components:

1. Breast Care Summary
2. Abnormality Flow Sheet
3. Reminder Sticker

Development (Year1 only):

A third component to our intervention was to implement a CRGS. The CRGS was placed in the charts of all eligible patients at the intervention sites in the four months proceeding the workshop as part of a permanent record. Please see **Appendix 4** for the CRGS. The CRGS includes:

- a) Fact/documentation form which we re-titled a Breast Care Summary. (**Appendix 4**). The documentation form summarizes the breast care activity during the baseline year as abstracted from the existing medical records and will serve to establish the time when a women becomes eligible for screening or diagnostic follow-up in the post intervention year.
- b) Guidelines for follow-up of abnormal findings-Please see the description of the process of development of the Guidelines in Task 4. The Guidelines are included in **Appendix 4**.
- c) Sticker placed on the outside of the chart to identify the patients who may be eligible for breast care. This serves as a reminder for the provider to check that patient's screening record for need for recommendation of CBE and/or mammogram.

In our proposal, we discussed also including the following:

- a) Breast history/physical exam form-currently in use at the Comprehensive Breast Health Clinic; it documents skin changes, nipple discharge, lumps, puckering, pain, scars, palpable mass, breast consistency in terms of smoothness and nodularity, axillary nodes information and provides additional space for summary of impression and overall plan of action.
- b) Mammogram requisition form and sample letter for patient notification about results.

These were not included in the CRGS because individual sites have their own forms for documenting breast history/physical exam and mammogram requisition. Therefore they did not want to change from the current forms that they are using.

The CRGS was developed using modifications of previous management algorithms published by Janet Osuch MD in the 1994 AMWA curriculum and in a book chapter from the 1996 edition of Harris, Diseases of the Breast. The other algorithms were modified from the 1998 AMWA curriculum of Morris and Osuch. Drs. Pathak and Osuch developed the modifications to reflect the content of the curriculum and to provide the uniform end-points of screening, work-up, or referral. One algorithm had not been previously published and was developed by Drs. Pathak and Osuch specifically for this grant. In total, seven algorithms were developed and printed on a single bright pink-colored sheet to be inserted into the chart to serve as a management reminder. The Breast Care Summary Sheet was developed to include the dates and type of breast care provided during the 15 months that the activities in the patient's chart were eligible to be abstracted for the appropriateness of breast care delivered. The Reminder Sticker was also bright pink-colored and is a graphic representation of a women of any ethnic origin performing breast self-examination. A copy of the CRGS is provided in **Appendix 4..**

Implementation (Year1 only):

Supplies were ordered for use in the intervention sites. These supplies were distributed to nurses as they began auditing. The placement of the CRGS in the medical record for each intervention site was as follows:

Site	Sticker Placement	Guideline/Breast Care Summary Placement
Kalamazoo	Outer front top section of chart	Top under divider section "Family Practice"
Midland	Outer front top section of chart	Top under section "Problem List"
Saginaw	Outer front top section of chart	Top under divider section "Physical Exams and Questionnaires"
St. Lawrence site of Sparrow/MSU Residency	Outer front top section of chart	Summary – Top under section "Problem List" Guidelines – Top under section "Health Maintenance"
Sparrow site of Sparrow/MSU Residency	Top of pink data sheet inside chart (site preferred this location as this section seen by provider at every visit)	Top under divider section "Health Maintenance"

Actual results of the number of women who meet the study criteria revealed the following approximate numbers at each site:

<u>Intervention sites:</u>	<u># Eligible:</u>
Kalamazoo Center for Medical Studies	1100
MidMichigan Regional Medical Center, Midland	2000
Saginaw Cooperative Hospitals, Inc.	1660
Sparrow/MSU – St. Lawrence site	1140
Sparrow/MSU – Sparrow and Mason site	1600
<u>Control sites:</u>	<u># Eligible:</u>
Genesys Health Systems, Flint	1035
McLaren Regional Medical Center, Flint	975
Munson Medical Center, Traverse City	1000
Providence Hospital, Southfield	2100 +

Because the audit period overlapped with the first three months of when the CRGS should be present in the chart, nurse auditors at intervention sites checked on a daily basis with the receptionist to establish if any of the women on their list had a scheduled appointment. Charts of women who had an appointment scheduled during that day had their CRGS inserted at that time. Thus, the CRGS forms were inserted into the women's chart prior to her first visit during the intervention year. Because of the delay in getting the auditing completed, a decision was made in late November to have the auditors stop abstracting and finish inserting the CRGS. This was completed in early to mid-December by all sites. A one-page reminder notice was placed in the mailbox of providers in November, 1999 to notify them that insertion of the CRGS was complete.

TASK 5(for Year1 only): Train nurse abstractors.***No change from Year One Annual Report***

- Hire 2 nurse abstractors at each site (8 sites).
- Bring all 16 nurse abstractors to MSU for a two day training workshop.
- Distribute to the nurse abstractors the required number of chart audit forms and CRGS kits to be inserted at the time of the audit into the charts of all age eligible women.

Hire 2 nurse abstractors at each site (8 sites): For each residency program site, we recruited and hired two part-time nurses not affiliated with the residency programs to conduct the audits of the medical records in their respective programs. All individuals hired were at least an R.N., with many being bachelor and master prepared. We also employed one M.D. Many had experience with chart auditing.

Bring all 16 nurse abstractors to MSU for a two day training workshop: On August 9 and 10, 1999, a nurse abstractor training was held on the campus of Michigan State University. Seventeen nurses were trained to abstract data related to breast care at the nine residency program sites (one program site – Saginaw – began with just one full-time nurse abstractor) and to insert the CRGS in the medical records of eligible patients (intervention sites). The training was led by Barbara Given, Ph.D., R.N., with assistance from Ping He, M.D., Dorothy Pathak, Ph.D., M.S., Principal Investigator, Suiying Huang, Data Coordinator, and Jodi Holtrop, Ph.D., Project Manager. Please see **Appendix 5** for the agenda and instruction manual for this two day training. The training included education on:

- Overview of the purpose of the study
- Lectures and examples on breast care documentation and follow-up.
- How to evaluate evidence of CBE being completed, findings of CBE recorded, referrals for mammogram, evidence that responses were made to abnormalities, and possible options for follow-up of these abnormalities.
- Chart audit content was reviewed in detail for each form that needed data entry. Examples were provided to show both process and content of the audit.

Sample cases were identified representing a variety of breast care concerns from the Clinical Practice Site at the Michigan State University Family Practice Center and Kalamazoo Center for Medical Studies. Names and all identifiers were blacked-out and these were used as sample cases. The auditors were paired for each site and given 10 practice cases to complete and successfully electronically transfer to the Data Coordinator. Investigators at MSU created the gold standard for the completed audits and Barbara Given, Ph.D., R.N. reviewed each of the practice cases from each of the auditors and completed the Kappa statistical test. Each pair entered several cases as a part of this practice session on the second day of training. Auditors went to their practice site and practiced on the 10 cases. Auditors were to revise these practice cases until he/she achieved a Kappa of 90% or higher as a measure of inter-rater agreement for the various components of the chart audit. Auditors were brought back to MSU for an additional day of training to ensure understanding of audit guidelines. This educational process and quality control assessment took additional time and delayed the beginning of the auditing process by approximately four to six weeks.

Once implemented, the auditors provided weekly reports on their progress. Email and telephone were used to deal with problems as they arose.

Distribute to the nurse abstractors the required number of chart audit forms and CRGS kits to be inserted at the time of the audit into the charts of all age eligible women.

After the auditors passed the quality control assessment, packages with at least 500 kits of CRGS were sent to each Intervention site. The kits included the guidelines that needed to be inserted into the eligible charts, the summary of breast care activity sheets and the stickers (see **Appendix 4**).

TASK 6(Year1 and Year2): Develop and adjust data management system for chart audit data.

For each of the forms what follows, Year1 describes development and Year2 changes made for Year2 abstracting.

The database was created in Access 97 in Year1 and in Access 2000 in Year2. It consists of four forms which are included in Appendix 1.

“Form I-Front End”**Year One**

The first form is called “Form I-Front End”, and contains general information about the patient. The information collected includes: the patient’s full name, medical record number, date of birth, and abstractor’s ID (all seventeen abstractors in nine sites were given unique abstractor ID’s.). One of the first steps on this form was to determine each patient’s eligibility code (Ecode). The five criteria to determine the Ecode; were as follows:

1. Is the patient a female?
2. Has the patient been seen in the last three years?
3. Was the patient’s date of birth between 8/1/1928 and 7/1/1959?
4. Has breast care been provided by a Family Practice Doctor (FPC)?
5. Has the patient been in contact with the physician for breast care between 8/1/98 and 7/31/99?

There are three values for the Ecode: 1, 2, or 3.

An Ecode of 1 means that patient has satisfied all 5 of the above criteria and is eligible for having their chart abstracted. Additionally at the intervention sites these patients were eligible for insertion into their charts of Chart Reminder Guideline System (CRGS described in Task 4 and included in Appendix 4).

An Ecode of 2 means the patient did not satisfy criteria 5, i.e there was no visit by the patient to the given Health Care Facility during the time period 8/1/98-7/31/99 (baseline year) and thus the chart is not eligible to be abstracted. At Intervention sites, these patients were still eligible for insertion into their charts of CRGS.

An Ecode of 3 means this patient is ineligible for this study because she did not satisfy one of the first 4 criteria.

After the Ecode was assigned, each patient was given a unique study identification number. The study identification number consists of six digits. The first digit of the identification number corresponds to the site number (there are nine site one number 1-9 assigned to each site). The second digit is the previously determined Ecode numeral. The remaining four digits are consecutive numbers starting with 0001. If the patient had an E-code of 2 or 3, after the patient identification number was assigned, the computer prompted the abstractor to discontinue chart audit, and go to a next patient. At the intervention sites, the abstractors proceeded with insertion of guidelines and breast activity form, for patients with Ecode2. For those patients with an Ecode of 1, the remaining pertinent information of the patient’s chart was abstracted and data entered on the laptop. At the intervention sites CRGS were then inserted into the chart.

The next important step that had to occur on Form I, was the calculation of the time period for which the chart was to be abstracted. It was determined by the research team, that if we are to calculate yearly screening rates, the relevant time period to abstract the breast care activity had to extend for 15 months prior to the last visit to the office. Every visit to the office, irrespective of the reason, was viewed as an opportunity for the family practice provider to review the current status of breast cancer screening for the patient. If there was no breast care activity during the proceeding 15 months of the given visit, the provider was expected to note this in the chart and make appropriate recommendations for breast cancer screening. Thus, when the abstractor entered the information located in the field labeled “Date of most recent office visit” (during the baseline year), the database automatically performed the calculation to determine the date fifteen months prior to patient’s most recent office visit. This fifteen-month interval was then audited for the occurrence of breast care activity. The final portion of Form I includes; total number of visits, and personal/family history of breast cancer (see Appendix 1 Form I for details)

Year Two

The changes to "Form I-Front End" include the following:

1) Additional questions on: a) date of the very first visit to the FPC provider and b) any documentation that patient left practice before 7/31/00. The reason for asking date of the first visit, was to evaluate how established the patient is in this particular practice. Asking question b) was to eliminate abstracting patients who left the practice in the middle of the abstracting year

Also to ensure that the new group of patients who were turning 40 as of August 1, 2000 were also included in the eligible group, the cut off date for establishing the eligibility criteria were changed to:

1. Was the patient's date of birth between 8/1/1928 and 7/31/1960?
2. Has the patient been in contact with the physician for breast care between 8/1/99 and 7/31/2000?

There are three values for the Ecode: 1, 2, or 3.

An Ecode of 1 means that patient has satisfied all 5 of the above criteria and is eligible for having their chart abstracted.

An Ecode of 2 means the patient did not satisfy criteria 5, i.e there was no visit by the patient to the given Health Care Facility during the time period 8/1/99-7/31/00 and thus the chart is not eligible to be abstracted.

An Ecode of 3 means this patient is ineligible for this study because she did not satisfy one of the first 4 criteria.

Study ID remained the same for all patients. Only new patients that were not abstracted into the database last year had a new StudyID assigned. The variable "Current year eligibility code" will allow us to identify all patients whose eligibility code changed between Year1 and Year2

At all intervention sites, we also checked if the Guidelines and Summary Breast Care Sheet were inserted for all eligible patients last year. We were also interested in knowing if the physicians used the Summary Sheet to document additional breast care. To implement this, we added two questions on the first form (Form I – Front-End Form). The first question checks if these documents were inserted and if additional information can be found on the Summary Sheet. The choices are: "Guideline Inserted"; "Guideline Not Found"; "Summary Sheet Inserted"; "Summary Sheet Not Found"; "Additional Information on Summary Sheet"; "No Additional Information on Summary Sheet". The second question reminded the abstractors to stamp these two documents since the team decided that it was important to identify them as part of a research project. The choices are: "Guideline Stamped"; "Summary Sheet Stamped"; "Both Stamped"; "N/A Guidelines"; "N/A Summary Sheets".

"Form II-Visit Entry"Year One

The next form is called "Form II-Visit Entry". This form records each breast care encounter the patient has received during the 15 months interval. The abstractor is required to record each date of breast care activity, and what type of contact was made.

On Form II the field labeled "type of contact" (breast care encounter) has the following options: office visit, doctor initiated phone consultation, patient initiated phone consultation, screening/routine/regular mammogram, diagnostic (regular) mammogram, diagnostic/cone compression/magnification mammogram, ultrasound result, fine needle aspiration (FNA) for cyst result; fine needle aspiration biopsy (FNAB) result, pathology report for radiological/image guided biopsy, pathology report for open biopsy; surgeon's letter, or Other.

If the option chosen is one of the following: Office visit, Doctor initiated phone consultation, patient-initiated phone consultation, or other, the rest of the form II is entered. If another type of contact was made, then abstractor goes directly to "Form III", which is the test result form.

On form II another field labeled "purpose of this visit/call" has the following options: screening/well women exam/annual exam, presenting symptom(s), follow-up of a previous abnormality, prompted by results of screening mammogram, prompted by results of other test(s), routine care/Other health problems, and Other. Only visits with some breast care activity are entered onto Form II. Based on this field we know why the patient was there and what was done during that visit with regard to breast care. From this point based on the information in the chart the abstractor identifies the person who performed the breast care/phone consultation, if patient presented with symptoms/signs, clinical breast exam (CBE) findings and quality of CBE documentation. The field of CBE findings is subcategorized into two headings of normal and abnormal. If an abnormal finding is recorded, the abstractor is required to record all the details of the abnormality (**See Appendix 1 Form-II**). Quality of CBE documentation is divided into five subgroups of drawings, inspection, palpation, lymph node examination, and other. For more specific details of data collection in "Form-II Visit entry" please see **Appendix1 Form-II**.

Year Two

This year's chart audit dates are from August 1, 1999 through July 31, 2000. Thus the 15 month abstracting time period calculated back from the date of last visit during that one year time period, took the abstractor into the Year 1 abstracting time period. . Therefore this year's abstractors also did quality control for data entered last year. They were asked to review all mammograms FOR THE ENTIRE ABSTRACTING PERIOD OF LAST AND CURRENT YEAR. If mammogram information was correct and no mammograms were missing, they were instructed to review OVERLAP PERIOD (definition and example later) for any errors. If NO ERRORS, chart abstraction and quality control review was complete. The abstractors were instructed to go to next patient. However, if (a) any mammograms are missing; (b) and/or wrong information is entered from mammogram (c) and/or wrong information entered for any encounter during the overlap period- the abstractors were asked to REVIEW ALL DATA ENTERED LAST YEAR, correct the already existing data-base and flag it for us. We provided comment box at the end of the form for the abstractors to record the changes they made on last year's data. This process will give us excellent quality control on last year's data.

Definition and example of overlap issues: A patient's most recent office visit for post intervention year, occurs on 11/15/99; going back 15 months takes us back to 8/15/98. However, her 11/15/99 visit was not breast related, and all her breast-related visits were between 8/1/98-7/31/99 and already abstracted last year. What does that mean in terms of abstracting for this year? .The overlap period for last year and this year is from 8/15/98 through 7/31/99. They will need to review the time of overlap for errors, i.e. check whether what was entered is correct. If they find that there are no errors for the overlap time, no mammograms were missing or have errors, they move on to the next patient. If they find an error on any encounter from the overlap period, or that a mammogram is missing or has an error on entry, then they go back and review all the visits that were entered last year. They first need to check all the mammograms during the two years' period and correct any errors.

However, since the team decided to define annual screening rates, as occurring during a 15 month time interval, in order to calculate post-intervention annual screening rates that would be comparable in terms of time period to those calculated for baseline year, the abstractors were asked to additionally abstract all breast care visits for the time period of 8/1/00 to 10/31/00. Thus, in reality, they were abstracting the 15 months going back from the last visit during the time period 8/1/99-7/31/00, plus 3 additional months from 8/1/00 to 10/31/00. This way we will be able to define post-intervention screening rates, as CBE or mammography performed during 8/1/99-10/31/00.

“Form III-test result entry form”

No change from Year One Annual Report.

The third form is called “Form III-test result entry form”. It consists of the breast care related test results that are found in the patient chart of a family practice doctor. It includes the results of mammogram, FNA, FNAB, ultrasound, and image-guided biopsy/open biopsy results. For each test performed options are provided as to the results obtained from that test (see **Appendix 1 Form III for more details**).

“Form IV-follow-up entry”

No change from Year One Annual Report.

The last form is “Form IV-follow-up entry”. This form is intended to record the follow-up that occurred or was recommended by the physician associated with each breast care encounter. It is divided into follow-up for normal and abnormal findings, and Surgeon’s letter. For normal findings the recommended follow-up can be: no follow-up, routine screening, time for twelve-month CBE, time for twelve-month mammogram, following ACS guideline, or the abstractor can type in alternative follow-up(s) if none of the fore mentioned applies. The recommendation can be done by the family practice doctor only (FPD), Radiologist only, both FPD and radiologist, surgeon, nurse practitioner, other, or undocumented. One of these options is given and recorded in the field named “recommended by” under the normal finding subcategory (see **Appendix 1 Form-IV**). The follow-up for abnormal findings was subdivided as follow-up for “specific abnormalities” and follow-up “common to any abnormalities” (see **Appendix 1 Form-IV**). The follow-up headings relative to “specific abnormal findings” were: breast mass/asymmetry initial approach, known breast cyst, known solid mass, nipple discharge, skin/nipple changes on observation, breast pain. The options that were specific for these major categories were those discussed in the curriculum and provided in the guidelines that were inserted into the charts. Some options were common to all abnormalities and consequently were included under the column “follow-up common to any abnormalities” These options included: call if problem worsens, routine screening, immediate mammogram work-up, interval follow-up, ultrasound, surgical referral, and undocumented. For additional recommendations relative to the follow-up procedure of an abnormal finding, the abstractor could type in the documentation in the comment box provided on the form.

Since a surgeon’s letter would occasionally be found in a patient’s chart, particularly those patients who had a biopsy of some sort, recommended follow-up by the surgeon was also recorded. The surgeon’s letter documentation allowed for recording of information regarding surgeon’s assessment of abnormality, additional tests performed, and subsequent recommended follow-up (see **Appendix 1 last page of Form-IV**).

Physician Breast Care Database Mechanics (Year1 and Year2)***No change from Year One Annual Report.***

The information collected in the four forms has been explained in the previous section and can be seen in **Appendix 1**. This portion of the report describes how these database "Forms I-IV" function for the data collection process.

Form one is the "Front-end" form. It describes the characteristics of interest and determines the eligibility of the patient. Each patient has a "Form one" assigned to their chart. If a patient is deemed ineligible, i.e. assigned an eligibility code of 2 or 3, the data collection process is stopped after the study I.D. is assigned. If they are assigned an eligibility code of one, the remaining "Front-end" information is collected. The question that associates a patient with the remaining "forms" is whether breast care was performed during the fifteen-month interval of interest (Question 4 on Form 1, see **Appendix 1**). If the answer to this question is "yes", the chart auditor will be prompted to continue onto "Form II" and describe the type of care given.

On "Form II" the type of breast care encounter found in the chart is described. If the patient is in contact with the doctor for an office visit, patient initiated phone call, physician initiated phone call, or a less specific reason, i.e. other, the various relevant parts of "Form II" are completed. If the type of breast care encounter were the results of a test, then the abstractor would be prompted to "Form III – Test Results". Lastly if the type of breast care encounter described in the charts is a surgeon's letter, then the abstractor is prompted to go to "Form IV".

For each "Form II" and/ or "Form III" entered, the auditor was expected to fill out a "Form IV". "Form IV" describes the follow-up recommended by the health care provider. Since an assessment plan is part of the physician's routine procedures for any type of breast care, "Form IV" was to capture this data and record it as follow-up.

For each patient the following numbers of forms are expected. Each patient should have an exclusive and individual "Form I". If the patient is eligible for the study and breast care was provided during the fifteen-month interval of interest, then the patient should have "Form II" filled out. The number of times "Form II" is filled out for a given patient, equals to the number of times breast care encounters occurred during the fifteen-month interval of interest. Additionally patients will have "Form III" filled out for every time "Form II" records the type of visit as a "test result". Lastly, for every "Form II" there will be a "Form IV" recording the follow-up recommended by the health care provider for that breast care encounter.

Overall a patient will have:

1. One "Form I".
2. If the patient is eligible and breast care is provided, at least one or more copies of "Form II" will be filled out, each recording a different type of breast care encounter.
3. If "Form II" describes the breast care encounter as a "test result", then a "Form III" describing the test result will be filled out.

For every "Form II" or "Form II and III" combined, there will be a "Form IV" describing the follow-up recommended.

Our database captured all patient encounters and phone calls during which breast care activities occurred. Any evidence in the medical record of a mammogram or CBE was accepted, such as a mammogram report, comments regarding refusals of a receiving a test or comments about why recommended tests were not performed. We also obtained information about mammograms/CBE performed at outside facilities or by other physicians such as OB/GYN, if they were documented in the medical charts.

TASK 7 (Year1 only): Training of evaluators for workshop.*No change from Year One Annual Report.*

- Hire and train patient instructors in evaluation of clinical breast examination technique
- Train faculty in evaluation of clinical breast examination (CBE) technique

Training of patient instructors

In April of 1999 we began recruiting patient instructors for the evaluation of CBE technique to be completed at the workshops at the five intervention sites. In July of 1999, nine patient instructors were trained for this purpose. Most of the patient instructors recruited were experienced patient models employed by the MSU College of Human Medicine for training of medical students.

The training was conducted by Henry Barry, M.D., M.S. and consisted of the following components:

- Brief orientation to the project and its goals
- Completion of breast examination and health history by Dr. Barry to determine the patient model had no existing breast health problems or conditions
- Instruction and demonstration of proper CBE technique and components
- Instruction on CBE examination evaluation form including what the component meant and how to properly complete the form

Patient instructors were then shown a 10 minute video "The Essentials of Clinical Breast Examination" California Department of Health Services, 1996. The video reinforced the concepts and instruction provided by Dr. Barry. Materials provided for the training are located in **Appendix 6**. Dr. Holtrop then completed employment paperwork and instructed patient instructors as to the location, time and date for workshops.

Training of faculty

Since the decision was made to utilize patient model trained in evaluating breast examination technique, faculty evaluators were not needed. Thus, no training occurred.

TASK 8 (Year1 and Year2): . Workshop on 'Screening and Diagnosis of Breast Cancer for Primary Care Physicians'

- Collect baseline data on knowledge, attitudes, and beliefs about breast cancer screening and early diagnosis using the 'Knowledge, Attitudes and Beliefs' Survey developed and used by Costanza.
- Collect baseline data on skills in CBE performance.
- Conduct the one day Workshop consisting of the Educational Session and Clinical Skill Course.
- Repeat all measurements from the pre-test at the end of the Workshop.

Workshops were conducted at Intervention Sites during Year1 and at Control Sites during Year2.*No change in the description of Workshops from Year One Annual Report.*

A three component intervention was utilized. These three components included:

1. Educational Session (ES) which included material on epidemiology of breast cancer, benefits of screening, guidelines for screening and follow up of abnormal findings, and principles of risk management.
2. Clinical Skills Course (CSC) which trained the physicians how to perform CBE and to interpret the findings. The education was then reinforced by the third component of the intervention which is the:
3. Chart Reminder/Guideline System (CRGS). The CRGS was placed in the charts of all eligible women at the four/five intervention sites, and included: a) a form summarizing breast care activity during the previous year;

b) guidelines for follow-up of abnormal findings, and c) identifying sticker to remind physicians that this patient is eligible for breast care.

Year One

The first two components of the intervention (ES and CSC) were organized into a one day, eight hour workshop. The title of this workshop was changed to "Comprehensive Breast Care for Primary Care Physicians" to better reflect the revised content of the curriculum. Although it was originally planned for the workshops to be held on weekends, the programs requested to close their clinics and hold the workshops on weekdays. The Lansing program was a new residency program as of July 1, 1999. It formerly consisted of two programs: Sparrow Hospital Program and St. Lawrence/MSU Program. It is now (as of July 1, 1999) the Sparrow/MSU Program. However, this program still has two locations for clinics: Sparrow site and St. Lawrence site. The total number of residents and faculty at this program was double the other programs. Therefore, there were five workshops held instead of four to accommodate this large number in Lansing. The following is a schedule of the workshops, when and where they occurred, and the number attending.

**Summary of Breast Care Workshops
Intervention Sites during 1999 (Year One)**

Date	Program	Total Participation N	Faculty* N	Resident N
July 15	Sparrow Hospital - St. Lawrence site	18	4 Physician	14
July 22	Saginaw Cooperative Hospitals, Inc.	28	3 Physician 1 NP	24
July 23	Kalamazoo Center for Medical Studies	22	5 Physician	17
July 27	MidMichigan Regional Medical Center - Midland	26	6 Physician 3 PA-C	17
August 5	Sparrow Hospital – Sparrow Professional building site	35	8 Physician 2 PA-C 1 NP	24

*Faculty includes physician faculty as well as Physician Assistants (PA-C) and Nurse Practitioners (NP).

As mentioned, the Educational Session and Clinical Skills Course were organized into a one day, eight hour workshop. The first four hours were designated as the Educational portion and the last four as the Clinical Skills Portion. Please see **Appendix 7** for an outline of the day for the workshop. The participant manual developed for use with the workshop can be found in **Appendix 2**. Instructors for the sessions included two of the following three instructors: Janet Osuch, M.D., Henry Barry, M.D., M.S., and Thomas Zuber, M.D. Laura Morris, M.D., who was initially designated as an instructor, declined participation.

Upon registration, the participants were assigned a name and color code for the purposes of identification and confidentiality. The color codes were useful in organizing the participants into rotating twice to three stations for evaluation at the second half of the day. Participants were then welcomed and given the pre-test for the knowledge, attitude and beliefs (KAB) scale (development of the KAB scale is described in the paragraph below). The remainder of the first four hours of the workshop was largely didactic and devoted to the Educational Session portion of the intervention. It was originally intended that the breast care curriculum written by Janet Rose Osuch MD for the American Medical Women's Association be used. This curriculum, first published in 1994, had been revised and expanded twice since originally written. It was decided that another major revision was necessary to accomplish the goals of the grant and to design the optimal learning experience for the participants. The revisions to the previously published curriculum are described in Task 2. A copy of the final curriculum can be found in **Appendix 2**. It incorporates principles of risk management into the didactic elements of the curriculum.

Instruction during this time covered:

1. Anatomy and Physiology
2. Epidemiology, Genetics, Risk Factor Counseling and Tamoxifen
4. Breast Cancer Screening and Evidence Based Medicine
3. Breast Pain and Work-up of Occult Mammographic Abnormalities
4. Work-up of Abnormal Findings on Clinical Breast Examination
5. Risk Management

After a lunch break, participants rotated through three stations (20 minutes each):

- 1) One station included a pre-test of their CBE skills utilizing trained patient instructors. Patient instructors evaluated the technique and completeness of the examination provided by the physician. See **Appendix 8** for a sample evaluation form that was completed by the patient instructors.
- 2) Another station was a pre-test of the physician's accuracy in locating breast lumps. This was assessed utilizing silicone breast models. See **Appendix 9** for the forms used by the physicians to record their responses with regard to the location, size, depth and hardness of breast lumps they identified.
- 3) A third station was to evaluate the knowledge, attitudes and behaviors (KAB) regarding breast care by having the physicians complete a post-test of the KAB scale (**Appendix 10**). The physician completed the pre-test prior to the Educational Workshop. Originally we intended to use the survey instrument developed by Constanza et al.¹ in their multidimensional intervention designed to alter physician breast cancer screening practices. However, upon careful review of that instrument and the content of our curriculum, the research team realized that we need to develop our own evaluation tool that would be based on the goals of the curriculum and the goals specified in the grant. Thus we looked at the survey developed by Constanza as well as two additional evaluation surveys, one developed by Dr. Osuch and the other by Dr. Zuber. Dr. Osuch submitted questions that she had formerly developed with Laura Morris, MD that they used in the Breast Cancer Education for DoD primary Care Managers. That curriculum was delivered to military personnel throughout the world in 1997 and was sponsored by the American Medical women's Association in conjunction with the DoD(HA) Breast Cancer prevention, Education and Diagnosis Initiative Work Group. Dr. Zuber submitted questions that he has formerly developed to evaluate the curriculum on Breast Cancer Detection, that he developed and teaches nationally to Primary Care Providers. Dr. Barry and Dr. Pathak looked at three evaluation tools, and identified from each instrument those questions that would derive from our educational goals and objectives and eliminated those that were not consistent with the goals and objectives of the curriculum. We needed to balance the questions for all the areas that we discussed in the curriculum. The areas were: Knowledge of risk factors/epidemiology, screening, abnormalities, appropriateness of follow-up, attitudes and beliefs, barriers and behaviors. For each instrument we identified which questions fall into the various domains. The next task was to ensure that within each of the domains we had a balance of the key content areas. After the questions were chosen, questions 1-19 were randomly permuted. Questions 20-24, which measured attitudes, beliefs and behaviors, were included at the end of the survey (**Appendix 10**).

After rotating through these stations, participants received the Clinical Skills Course portion of the intervention. During this time, we trained the physicians in the performance of CBE and in documenting and interpreting the findings. This educational approach is based on the work of Fletcher et al., and Pennypacker et al.²⁻⁴ We taught CBE using the "Lump Discrimination Teaching Model-TM-LD-T", a hemispherical model developed by Pennypacker with transparent skin and lumps of varying size, hardness and mobility embedded against normal nodularity. Lump sizes ranged from 3mm to 1.0 cm in diameter. The participants were taught the six components of the CBE technique performance which included using: 1) their finger pads; (2) middle three fingers; (3) circular motion; (4) systematic pattern; (5) sequence of varied superficial, moderate, and firm pressures; and (6) thoroughly covering the total area of the breast model. This part of the program included reinforcement of the Clinical Breast Examination (CBE) training using professionally produced videotape. The California Department of Health Services made the instructional video with Janet Osuch, M.D. as a consultant.

After this training, participants then rotated through three stations again in the later afternoon to assess any improvements in CBE skills (patient models station) or accuracy in finding lumps (silicone model station). The third station allowed participants to practice using the **GAIL** model for risk assessment. Six practice cases were adapted by Dr. Osuch from the Breast cancer risk assessment and counseling kit, an educational resource provided by Astro-Zeneca Pharmaceuticals, manufacturers of Tamoxifen citrate, a drug used to reduce the risk of breast cancer in women determine to be at high risk (**Appendix 11**).

Throughout the day, risk management principles and guidelines for follow-up of abnormal findings were emphasized. Participants were also trained in the use CRGS.

RESULTS from Evaluation of the Year1 Workshops.

At the end of the Workshop participants were asked to fill out a written evaluation of the Workshop (**Appendix 12**). Overall, 77% of the participants rated the Workshop as "Excellent", 20% rated it as "Good" and 3% rated it as "Satisfactory". No one rated it as "Poor". Additionally the participants were asked for comments and suggestions on how to improve the Workshop. All comments are listed in **Appendix 12**.

Year Two

In the second year of the project, workshops were offered to the residency programs selected as control sites. The workshops followed the same content and agenda as offered in year one. One residency program, St. Mary's Medical Center in Grand Rapids, was included, although this program is not included in the study. This program was originally included as a study site, than later dropped because of a closely resembled study occurring at that site by another investigator. However, this site is part of the MSU Residency Network and was deemed important to be included in the workshop offering.

Summary of Breast Care Workshops Control Sites during 2000/01 (Year Two)

Date	Program	Total Participation N	Faculty* N	Resident N
August 31, 2000	Genesys Health System, Grand Blanc	42	Physician 8	34
October 12, 2000	McLaren Regional Medical Center, Flint	20	Physician 3	17
October 24, 2000	St. Mary's Medical Center, Grand Rapids	32	Physician 8	24
December 13, 2000	Providence Hospital, Southfield	41	Phys 11 PA-C 1 NP 1 Med st 2	26
January 22, 20001	Munson Medical Center, Traverse City	23	Physician 6 NP 2	15

*Faculty includes physician faculty as well as Physician Assistants (PA-C) and Nurse Practitioners (NP).

RESULTS from Evaluation of Year2 Workshops.

Evaluation results from the workshop from year two resulted again in very positive responses. Overall, 73% of the participants rated the Workshops as "Excellent", 26% rated it as "Good", and 1% rated it as "Satisfactory." Complete results and participant comments can be found in **Appendix 12**.

TASK 9 (Year1 and Year2): Data entry and analysis of data collected at time of intervention:

- Pre-post outcome measures on knowledge, attitudes, and beliefs about breast cancer screening and early diagnosis;
- Pre-post outcome measures on CBE skills

During Year2, the Workshops were delivered to the Residency Programs serving as Control Sites. The analysis for the pre-post outcome measures on knowledge, attitudes, and beliefs about breast cancer screening and early diagnosis and the pre-post outcome measures on CBE skills were conducted in the same manner as described in Year One Annual Report. The description of these procedures follows below.

Immediate effect of the educational session on knowledge attitudes and beliefs of breast cancer screening and early detection (Year1 and Year2).

The survey instrument (Appendix 10) was completed before and after the educational session to assess physicians predisposing attitudes toward, and level of knowledge of, screening, early detection of breast cancer, and appropriateness of follow-up for specific abnormalities detected either by CBE or mammogram.

The pre and post survey form created in the database consisted of physician identification number, site of intervention, date intervention was performed, the 24 questions of the survey, and a comment box for the data entry person to write any additional physician comments (See Appendix 10). The physicians' answers to the survey were entered directly from the survey to the computer.

Immediate effect on CBE competence (Year1 and Year2).

Two approaches were used:

1) Assessment of ability to detect lumps by CBE (pre-post CSC): For evaluation of CBE competence in detecting lumps, we used 6 silicone models known as the "UNC Series", developed by Pennypacker and colleagues at the University of Florida, Gainesville and the Mammatech Corporation. Each silicone model has a volume of 250 mL, simulates the breast of a 50-year-old woman, and contains simulated background fibroadenomatous tissue. Across the 6 models (A, B, C, D, E, F), there are 18 lumps which vary in size (1.0, 0.5, and 0.3 cm in diameter), hardness (60, 40, and 20 durometers), and depth of placement (medium and deep). Five models contain between one and five lumps each and one model contains no lumps. We had 6 sets of 6 silicone models each. Each set was assigned a color. Forms with two breast models were printed on 6 different colors of paper. These forms together with the models were placed on three separate tables with 2 models from each color present on each table (Table I, Table II, Table III). The order of models within a given color was randomly chosen so that adjacent colors on the table did not have the same models. Colored forms were placed by the models and participants were asked to mark on them the location, size, depth and hardness of the lumps detected. During the post-test participants were instructed to choose a different color set than the pre-past. This ensured that the order in which they examined the 6 breast models was different on the pre and post-test. Participants were asked to assume the breasts are those of a 50-year-old asymptomatic women with no personal or family history of breast disease. Using these models we evaluated physicians' ability to detect lumps and properly document them on the form. These forms were subsequently coded and for each physician, we calculated their sensitivity and specificity of lump detection (Hypothesis 2b).

Each physician examined six silicone breast models. For each of the silicone breast models the location, depth, size and hardness of the lumps was known. Each physician was asked to report the location, depth, size and hardness of lumps in the silicone breast models and to record this information on the silicone breast model form (see Appendix 9) Each form was composed of two breasts divided into quadrants, and the circumference for each breast was directly proportional to the actual model. In addition to the physician description of the location, depth, size and hardness of the lumps in each individual breast, the physician ID, date of intervention, and site were also collected.

A key coding sheet was developed by Drs Barry and Pathak with regard to the location and number of actual lumps in each model. This allowed us to quantify the total number of lumps correctly detected and number of false positive lumps specified for all six breasts for each physician. Thus we were able to calculate sensitivity and specificity of lump detection for each physician and an average for site. For a lump to be considered properly detected by a physician, the lump recorded by the physician must have been within a 4-cm diameter circle (during Year One Annual Report), and have been recalculated for 2 cm diameter circle for each lump. The location of the 2/4-cm diameter circle was determined as having an origin defined by the center of the actual lump located in the silicone model. Thus for this year we repeated the calculation of sensitivity and specificity using a more stringent criteria for the calculation of true and false positives (see **Appendix 13**).

Using the summation of the number of correctly detected lumps by the physician and knowing actual number of lumps sensitivity could be calculated. Sensitivity was defined as the percentage of the 18 lumps a physician correctly detected (within 2 cm diameter) in all six silicon breast models. The mathematical definition for sensitivity was the following:

$$\text{Sensitivity} = \frac{\text{The number of correctly identified lumps (x)}}{\text{The total number of lumps in all breasts (18)}}.$$

Specificity equaled one minus the percentage of the six breasts examined with at least one false positive. False positive is defined as the number of breasts with at least one nonexistent or incorrectly marked lump, divided by the total number of breast models, which was six.

False positives were determined with the unit of analysis being breasts. A breast was considered to be false positive if the physician reported a lump that did not exist, or did not properly place the lump within the 2cm circle criteria. Using this unit of analysis specificity was calculated as one minus, the quantity, the number of breasts with at least one nonexistent or incorrectly marked lump indicated by a physician divided by the total number of silicon breast models examined by the physician, which were six. The mathematical formula definition of specificity is the following

$$\text{Specificity} = 1 - \frac{\text{The number of breast models with *at least one* false positive}}{\text{the total number of breast models}}$$

2) Assessment of CBE technique (pre-post CSC): We utilized patient models to assess the technical quality of CBE technique used by participants. We trained the live models in evaluating the technical quality of CBE techniques using the evaluation scheme described below. The live models rated the participants before and after training using an existing 6 point evaluation instrument (**Appendix 8**). This instrument assesses the six components of the CBE technique performance which includes using: 1) their finger pads; (2) middle three fingers; (3) circular motion; (4) systematic pattern; (5) sequence of varied superficial, moderate, and firm pressures; and (6) thoroughly covering the total area of the breast. Outcome measures to be evaluated are the proportion of correctly conducted components of the CBE and the area of the breast covered during the CBE.

Databases for the evaluation of the immediate effect on CBE competence (Year1 and Year2).

The data collected for each resident physician was a pre and post form for each of the following components: a survey, a live model CBE, and silicone model breast exam (see **Appendices 8,9,10**). Databases were created using Microsoft Access 97 in Year1 and Access2000 in Year2, for each of the three components, and then dichotomized into pre and post portion of information, totaling 6 databases (i.e. pre and post survey, pre and post live model CBE, and pre and post silicone model breast exam). All data collection questions and items remained the same for both pre and post observations. The data were analyzed using the SAS program to determine whether statistically significant improvements could be observed for the various outcomes of interest.

For the Patient Instructor CBE in addition to individual data points entered, a summary score for the area missed during examination was calculated. The actual process of scoring is described below, and the original form is included in **Appendix 8**. Each of the form sections, Communication, Positions, Perimeter, Pattern of Search, Palpation, Pressure, and Patient education were entered from the original to the computer as checks marks. Additional information such as which breast was being examined, date of exam, physician identification, patient instructor, total time of exam, time per breast, and site were also entered into this database form

The mapped breast area in the upper right corner of the live model CBE form needs further explanation. The live models were instructed by the investigators of the grant to mark an "x" in concordance with the area on the form where the physician did **NOT** palpate them. The heavy lined boundaries were explained to the women, so that it would be known if the physician had palpated the entire area. This mapped area was later sectioned into five segments. The segments were labeled and described as the areola, upper inner quadrant (UIQ), lower inner quadrant (LIQ), upper outer quadrant (UOQ), and lower outer quadrant (LOQ). These areas remained constant for both right and left breast exams (see **Appendix 14**). The number of boxes comprising each segment was summed and is displayed in the table below. The area **MISSED** for each section of the breast was calculated as follows: the numerator was defined as the number of boxes marked "x" in that area of the breast and a denominator was the total number of boxes comprising that area of the breast. Using Access 97 to calculate and report these percentages, the pre and post exams for each physician were compared using SAS to see if their technique improved after intervention.

Area of breast	Number of squares in each area
Areola	4
Upper Inner Quadrant	9
Lower Inner Quadrant	32
Upper Outer Quadrant	32
Lower Outer Quadrant	32

RESULTS of the Pre-Post Training Evaluation for All Sites (Year1 and Year2).

Appendices 15, 16 and 17 list the results of the workshops from pre (beginning of the workshop day) to post (end of the workshop day) for the Knowledge, Attitude and Behavior Scale, Live Model Examination, and Silicone Model Examination respectively.

For the Knowledge, Attitude and Behavior Scale; the proportion of correct answers to the 19 knowledge questions changed from a mean of 50% (range 10 % to 86%) before to 77% (range % to 98 %) after the training ($p<0.0001$). Please see **Appendix 15** for the complete results for each question and each site. For the Live Model Examination, the average score (out of five total components) of physicians correctly using all five components of palpation technique rose from 3.3 to 4.3 after the training ($p<0.0001$) and the percent whoscored 5 out of 5 rose from 32.9% pre to 68.5% post. The mean percent of the total area examined during CBE increased from 87.2% (range 83.3% to 89.7%) before to 97.7% (range 91% to 99.7%) after the training ($p<0.0001$). Please see **Appendix 16** for the complete results. For the Silicone Breast Model Examination, the sensitivity for location of the breast lump, defined as the proportion of 18 lumps correctly detected (within 2 cm radius), increased from 59.8% at baseline to 65.8% after the training ($p<0.001$). The specificity defined as percent of models without a false-positive, rose from 35.1% before to 39.5% after the training ($p=.011$). Please see **Appendix 17** for the complete results. For all variables under consideration, except for specificity, the residencies did not differ with regard to the level of improvement. For specificity there was a significant difference between residencies. Therefore for all outcomes other than specificity, the results from all intervention residencies were combined and

paired t-test was used for the final analysis. For specificity we will report our results specific for each residency.

Thus, this study shows that a comprehensive approach to training was effective in improving short-term knowledge, technique, sensitivity and specificity of CBE, which should translate into improved detection of breast cancer.

TASK 10 (Year1 only): Baseline chart audit (for the baseline year 8/1/98-7/31/99).

No changes from Year One Annual Report

Chart Audit Process:

It was initially proposed that auditors would enter data on a paper audit form and send via Federal Express on a weekly basis. Then, a student would enter data. A decision was made early in the project to handle the data electronically. Thus, the data entry forms were created in the Access database program and placed on laptop computers. Each site was provided one laptop computer in which to enter and transmit data. Each abstractor was provided an MSU email account and encouraged to utilize this account for communication with project staff. Thus, the nurse abstractor training also included instruction on using the laptop computer, entering data on the computer, using the email account, and electronically transferring data.

A list of names of patients whose charts were eligible for audit were generated in July and August, 1999. Auditors began abstracting data in September and October, 1999. The table below lists the residency program sites, number of records to be audited and progress with completion.

<u>Intervention sites:</u>	<u># Eligible</u>	<u># of charts abstracted</u>
Kalamazoo Center for Medical Studies	1100	905
MidMichigan Regional Medical Center, Midland	2000	1735
Saginaw Cooperative Hospitals, Inc.	1660	1319
Sparrow/MSU – St. Lawrence site	1140	946
Sparrow/MSU – Sparrow and Mason site	1600	1106
 <u>Control sites:</u>	 <u># Eligible:</u>	 <u># of charts abstracted</u>
Genesys Health Systems, Flint	1035	990
McLaren Regional Medical Center, Flint	975	563
Munson Medical Center, Traverse City	1000	941
Providence Hospital, Southfield	2100	2036

For Intervention sites, the information obtained on the baseline chart audit form is summarized using the Breast Care Summary Form in the CRGS. This is readily accessible to the physician for determination of time when each patient becomes eligible for annual CBE and mammogram during post-intervention year.

TASK 11(Year1 only): Quality control assessments of baseline chart audits at each practice site.

The process for Kappa calculation remains the same for both years and is described below. Results for Year2 Quality control are described in Task 18, page 34.

Description of process used in Kappa calculations did not change from Year One Annual Report.

Quality control audit process: Two graduate students in Epidemiology were hired for the purpose of visiting the participating residency program sites and conducting the quality assurance audits. The students were trained in a one-day intensive training by Barbara Given, Ph.D., R.N. on October 5th, 1999. The training manual provided to the nurse abstractors was used as a reference for this training (see **Appendix 5** for training manual). The graduate students were also required just as the nurses were, to complete the same 10 practice cases and review their abstracting with Dr. Given. Dr. Given completed the Kappa test for each to determine accuracy of their auditing. A 100% Kappa was required from the graduate students since they were to serve as gold standard for the abstractors.

Quality assurance checks for the nine sites were completed during November 1999 through January 2000, according to the following schedule:

November 9, 1999 - St. Lawrence, Lansing
 November 12, 1999 - Kalamazoo
 November 16, 1999 - McLaren, Flint
 November 19, 1999 - Saginaw
 November 23, 1999 - Traverse City
 December 02, 1999 - Providence, Southfield
 December 10, 1999 - Genesys, Flint
 December 16, 1999 - Midland
 January 17, 2000 - Sparrow, Lansing

During these quality assurance checks, 12 records were randomly selected from each auditor's patient eligibility list. Charts were first sorted on their eligibility code 1, 2, or 3. Within the eligibility code of 1, charts were sorted on the number of breast care encounters. The distribution of the 12 charts chosen for quality control audit was as follows: 2 with Ecode=3; 2 with Ecode=2, and 8 with Ecode=1; Within the 8 charts with Ecode=1, 2 charts had 1 encounter, 2 had 2 encounters, 2 had 3 encounters, 1 had 4 encounters and 1 had 5 encounters or more

The graduate students audited the same selected records as had been completed by each auditor. Suiying Huang, Data Manager, then completed Kappa tests for the charts audited by both the nurse abstractor and graduate student (**Appendix 18**).

Kappa Calculation for Quality Control:

To perform the quality control we chose the relevant fields in the database for which a kappa value could be calculated. The Kappa value is the ratio of the agreement actually observed minus the agreement expected by chance, divided by 1 (which corresponds to perfect agreement) minus the agreement expected by chance:

$$K = (P_A - P_C) / (1 - P_C)$$

Kappa statistics were derived using the SAS program. The simple kappa coefficient measures the agreement between the abstractors beyond what could be expected by chance.

Displayed below are three examples of the types of Kappa calculations performed on the data. These examples display the data collected, the SAS code used, and the output produced by SAS.

Examples of Kappa calculation:

1. For fields with numerical value entries:

The following table is the data entered by both the abstractor and quality control person for the question "Total numbers of visits within 15 months, including the most recent visit" (question #3 on Front End Form). In this case these numerical values were compared. In the table you will notice the discrepancy between the abstractor and quality control for patient number 4.

	Abstractor	Quality Control
Patient 1	6	6
Patient 2	2	2
Patient 3	2	2
Patient 4	5	6
Patient 5	3	3
Patient 6	4	4
Patient 7	6	6
Patient 8	9	9

After this table is made, the data is input into SAS for Kappa calculation. The reason that there are only 8 patients is that 4 charts had either Ecode 2 or 3 and consequently this portion of Form I was not filled out. The following output was obtained.

Statistic	Value	ASE	95% Confidence Bounds	
Simple Kappa	0.8431	0.1430	0.5628	1.1234
Weighted Kappa	0.9500	0.0501	0.8517	1.0483

2. For fields labeled 0 or 1:

For fields with only 0 or 1 value, i.e. unchecked versus checked boxes respectively, in the ACCESS Database, a different method of Kappa calculation was used. An example of a scenario where this occurs is on form II-Visit Entry. In this section the abstractors is asked to record CBE documentation. One portion of the section is to indicate if the lymph node examination is documented. The following table was made comparing the abstractor versus quality control observations of whether during the CBE the doctor documented a lymph node examination. In this example "1" signifies lymph node examination was documented and "0" means that it was not.

	Abstractor	Quality Control
Visit 1	0	1
Visit 2	0	0
Visit 3	0	0
Visit 4	0	0
Visit 5	0	0
Visit 6	0	0
Visit 7	1	1
Visit 8	1	1
Visit 9	0	0

After this table is made, the data is transferred into SAS for Kappa calculation. For the 8 patients there were 9 office visits where CBE was performed. For six of them there was no documentation of lymph node examination, while for 3 of them it was documented. The abstractor missed one documentation record.

Kappa	0.7273
ASE	0.2474
95% Lower Conf Bound	0.2424
95% Upper Conf Bound	1.2121

3. Situations where Kappa is calculated to be 0%:

There are some fields where the calculated Kappa value equals 0%. Often this happens when the marginal totals are very unbalanced i.e, if we have 10 charts, for example 9 provide answer 'yes' and only one provides answer 'no'. In those situations the Kappa statistics is not the best way to represent the data and in those situations the percent agreement is more appropriate. When such situations arose in our data, we have included in parenthesis the percent agreement

An example is included for bilateral mammogram findings. For a bilateral mammogram, the abstractor is required to record mammogram findings for both breasts. However, sometimes the abstractors would forget to record the bilateral mammograms findings for one of the breasts. Within this group of 12 patients only 4 had bilateral mammograms. The following table is the summary of bilateral mammogram documentation results for the 4 patients with mammogram reports in their charts. In this case "1" signifies mammogram documentation and "0" signifies no mammogram documentation. In this scenario the abstractor missed recording the mammogram documentation compared to the quality control for patient 4.

	Quality Control	Abstractor
Patient 1	1	1
Patient 2	1	1
Patient 3	1	1
Patient 4	1	0

Kappa	0.0000
ASE	0.0000
95% Lower Conf Bound	0.0000
95% Upper Conf Bound	0.0000

On the other hand, the percent agreement is calculated to be:

$$(4 - 1) / 4 = 75\%$$

RESULTS from Quality Control (Year1 only): Year2 results are described in Task 18, page 34.

Tables 1-5 in Appendix 18 provide Kappa values for each of the 17 abstractors. The fields chosen for Kappa calculations were those that the research team considered critical for dermination of outcome values specified in study hypothesis. Forty three fields were subjected to quality control evaluation:

- 1) **4 from Form I (General Information)**-Eligibility Code, date of the most recent visit, total number of visits within 15 months, total breast care related encounters;
- 2) **5 from Form II (Visit Entry form)** - Type of contact, presenting symptoms(lump) in the right or left breast, CBE documentation with regard to inspection, palpation, lymph node examination, and whether there was abnormal finding with regard to lump in the right or left breast.
- 3) **15 from Form III (Test results entry form)** - For mammogram findings, the 6 categories of mammogram classification for both right and left breast (12 fields) and for 3 outcomes for FNA findings-resolved/not bloody, bloody fluid, residual mass.
- 4) **12 from Form IV (Follow-up form)** - Follow-up undocumented, routine screening, 12 month CBE, 12 month mammogram, immediate mammogram, extra views, cone compression, magnification views, interval mammogram, interval CBE, ultrasound, surgical referral.
- 5) **4 from Form IV (Surgeon's Letter)** - Further tests, evidence of malignancy, follow-up in primary care office, follow-up in surgeon's office.

The "*" in the tables specifies that Kappa value was 100%. Over 90% of Kappa values were 100% and the remaining ones were either excellent (>80%) or Very Good (60-80%) Only 2 kappa values were less then 60% and they were 58% and 59%. We attribute this high quality of abstracting to the intensive training that the abstractors received, the requirements by Dr. Given that for the 10 practice cases their Kappa values be at least

90% prior to being allowed to abstract in the field, and the additional day of training that they received right before going into field after they had the opportunity to practice the 10 cases and ask questions that allowed them to properly enter the data. Although this process has delayed our abstracting by at least six weeks, it guaranteed for us high quality of data.

TASK 12 (Year1 and Year2): Data entry and analysis of baseline chart audit.

- Data entry
- Data analysis of baseline outcome measures

Data Entry (Year1 and Year2):

It was determined that the data entry would occur at the point of the nurse abstractor rather than by a hired student employee. Therefore, data entry coincided with the chart audit process. As the nurses audited the medical records of the eligible patients, they entered the data directly onto the laptop computer. This was electronically transferred by the FTP (file transfer protocol) process on a weekly basis.

Each week completed chart audits were sent to Suiying Huang, Data Coordinator. A weekly report was also sent to Barbara Given, Ph.D., R.N. relating the number of hours worked, the number of record audited and any other questions/concerns. Items needing clarification or completion were returned to the auditors for action. The number of returned chart audits for each site was tracked for each auditor and reports were generated on the completion rates for each auditor.

Data analysis of the baseline outcome measures (Year2 only):

Data analysis of the chart abstract information for the baseline year started in the spring of 2000 and is continuing. Drs. Pathak and Osuch performed the initial screening of any charts identified with an abnormal finding. The follow-up of each abnormality is being judged as appropriate or inappropriate according to the algorithms developed for the curriculum. In all cases where management is judged inappropriate, and in any equivocal cases where judgement could be swayed, the charts are discussed in a team meeting with all of the investigators involved in clinical care so that a consensus judgment can be made.

The outcome measures of interest for the primary hypothesis (based on chart audits) are changes in pre-post levels of: 1) proportion of women receiving CBE and mammography; 2) rate of documentation of findings; 3) time to follow-up of abnormal findings; and 4) rate of appropriate follow-up for abnormal findings. We will test the null hypothesis that for a given outcome measure, the changes from pre-post intervention are the same for sites in the intervention and control arm of the study, versus the alternative hypothesis that these changes are significantly greater for the intervention arm.

Statistical analyses for this study will take into consideration the cluster randomization of intact physician groups. The primary outcome measures for the intervention effect will be based on comparison of the baseline measures of interest with those for the intervention year.

Screening rate for Baseline Year (Year2 only):

We calculated the patient-specific annual screening rate for CBE, mammography, and both, in all 9 clinics, among women 40-70 years old. For this study, annual screening rate will be defined as screening occurring during a fifteen-month time frame between 5/1/98 and 7/31/99.

Summary reports of all breast care activities for each patient was generated and reviewed to confirm eligibility. If patient's breast care is provided by other physicians such as an OB/GYN, or if the patient is being followed by an oncologist, the abstractors were instructed to record this into the database, and the patient was excluded from our screening rate (Figure 1 – flow chart, see appendix). Mammogram ordered for diagnostic rather than for screening purposes, such as mammograms ordered to follow up of a previous abnormality or as diagnostic due to abnormal

CBE were not considered to be screening mammogram and these patients were excluded from the mammography screening rate. Similarly, patients with diagnostic CBE were also be excluded. Another special situation was that if CBE or mammography was/were ordered after 7/31/99, and the patient's total number of visit during the last 15 months was less than or equal to 3, we excluded her from the CBE or mammogram screening. Abstractors were instructed to write all comments concerning each breast care related encounters, such as refusal and reason why test were not done, in the provided comments boxes. All comments were reviewed manually.

For this analysis, women were classified as being "screened" if they had received at least one CBE or Mammography, or both within the 15-month period. The following screening rates or issues related to screening rate were generated:

- (1) CBE screening rate defined by actual CBE performed in asymptomatic women
- (2) Mammography screening rate defined by actual mammography performed in asymptomatic women
- (3) Breast Cancer (or BC which includes both CBE and Mammography) screening rate defined by both CBE and mammography performed in asymptomatic women.
- (4) The rates for CBE that are ordered, regardless of whether or not they were performed.
- (5) The rates for mammography that are ordered, regardless of whether or not they were performed.

Screening rates are listed in **Appendix 19**. When (Prelim) appears after the Site number, it means that for that site screening rates were calculated only for individuals who did not have any abnormalities reported during that 15 month time interval. On the average abnormalities are reported for approximately 10% of charts abstracted. For sites 1,3 and 6, where calculation of screening rates was a part of Master's thesis, women with abnormal findings were also reviewed for having screening CBE and/or mammogram. This process is ongoing for all remaining sites and information will be completed for the Final Report. Overall screening rates varied depending on the definition of screening (**Appendix 19**). For example, CBE was performed in 46.7% and 52.1% of women 40-49 and ≥ 50 years old respectively. For mammogram done these rates were 31.5% and 50.7% for 40-49 and ≥ 50 years old respectively. For both modalities done it was 23.8% and 37.9% for 40-49 and ≥ 50 years old respectively. These values vary by site and are provided in **Appendix 19**. Our results to date underline two important points: (1) the current breast cancer screening rates for CBE and mammography individually or combined are unacceptably low (2) when screening is recommended, (comparison of ordered vs. done) compliance with the recommendation is above 98% and accomplished 90% of the time within 3 months (additional analysis). To meet the Healthy People 2000 recommended mammography and CBE combined screening rate of 60%, interventions to improve these findings at FPC will be urgently needed. During the Fall when we calculate post intervention screening rates we will assess the impact of this Workshop on breast cancer screening rates.

TASK 13 (Year2 only): Assessment of retention of training effect**1. Train evaluators:**

- Hire and train live models in evaluation of clinical breast examination technique.
- Train faculty in evaluation of clinical breast examination technique

2. Collect follow-up data on knowledge, attitudes, and beliefs about breast cancer screening and early diagnosis using the “Knowledge, Attitudes and Beliefs” Survey developed specifically for this study.

3. Re-evaluate skills in CBE performance.

4. Repeat all measurements from the original pre-test.

Train Evaluators (Year 2 only):

On April 26, 2000, three additional patient instructors were trained for the purpose of conducting the evaluation at the reassessments held in May and June of 2000. The training will encompass the same components as the initial training held in July of 1999 for the initial patient instructors (see Task 7 and Appendix 6).

On August 22, and October 2, 2000 additional trainings were held to hire and train five additional patient instructors for the control site workshops held in the fall of 2000 and winter of 2001. All year two patient model trainings were conducted by Henry Barry, MD, MS and covered the same content and format.

Collect follow-up data on knowledge, attitudes, and beliefs about breast cancer screening and early diagnosis using the “Knowledge, Attitudes and Beliefs” Survey, re-evaluate skills in CBE performance, and repeat all measurements from the original pre-test. (Year 2 only)

We collected data on knowledge, attitudes, and beliefs, ability to detect lumps and technique of CBE, during re-evaluations which are scheduled, as described below:

**Summary of
Reassessment Workshops 2000**

Date	Program	Total Participation
May 4	Sparrow Hospital-St. Lawrence Campus	16
May 18	MidMichigan Regional Medical Center-Midland	27
May 19	Saginaw Cooperative Hospitals, Inc.	24
June 8	Sparrow Hospital-St. Lawrence Campus – Sparrow Site	23
June 9	Kalamazoo Center for Medical Studies	10

Each re-assessment lasted for two hours. For one hour, participants rotated through three stations: 1) Collection of data for the KAB survey, 2) technique of CBE and 3) lump detection skills. These stations were conducted just as they were in the original workshops (please see Task 8). During the second hour, a focus group was held to assess relevance of the curriculum and the participant's ability to utilize the information and skills gained during the workshop, in his/hers daily care of patients. Please see Task 15 for a specific description of the focus groups. To best manage time, the total participant groups were split into two and switched roles (i.e. one group did three stations first and the other did the focus group first and then the groups switched).

TASK 14 (Year2 only): Data entry and analysis of data collected for the evaluation of training retention:

- Data entry of outcome measures on knowledge, attitudes, and beliefs about breast cancer screening and early diagnosis
- Data entry of outcome measures on CBE skills
- Data analysis of knowledge, attitudes and beliefs about breast cancer screening and early diagnosis
- Data analysis of outcome measures on CBE skills
- Compare data from Task 16 (retention of training effect) to data from Task 8 (pre-training and immediate post-training)

For the re-testing participating physicians were assigned the same color/number as they had during the original training. The collected data was entered into the databases developed for the assessment of immediate effect of the curriculum on the physician's cognitive (KAB survey) and clinical (CBE technique and lump detection ability) skills. Comparisons were made between individual's scores on the post-test at the time of training and on the current re-testing.

Data for each resident physician was collected at reassessment for each of the following components: a survey, a live model CBE, and silicon model breast exam (see appendix 1). Databases were created using Microsoft Access 2000 for each of the three components, and categorized according to when they were collected pre, post, and reassessment, therefore totaling 9 databases (i.e. pre, post, and reassessment survey, pre, post, and reassessment live model CBE, and pre, post, and reassessment silicon model breast exam). All data collection questions and items remained the same for pre, post and reassessment observations. This data was analyzed using the SAS program to determine whether statistically significant improvements in all components could be observed.

The description of the methodology used for calculating retention scores for KAB survey, and clinical skills such as CBE technique and lump detection ability (outcome measures of interest), is defined in TASK 9.

RESULTS:

Appendices 20-22 list the results from the pre-reassessment and post-reassessment comparisons for the five intervention sites.

The results for the Knowledge, Attitude and Behavior Scale are provided in Appendix 20. For each question, we provide %correct on pre, % correct on post, %correct on reassessment. The individual sites differ somewhat, however, the mean for the 5 intervention sites, show that in general reassessment values are not as high as post, but are higher than pre indicating retention of the material thought during the Workshops. The percentage of correct answers ranged between 13% to 86%, for pre, 54% to 97% for post, and 30% to 96% for reassessment.

For coverage of the breast area during the examination, significant improvement (87.2% to 94.4%) was made from the pre-test to reassessment for the live model examination. Unfortunately, there was a loss from the post-test to reassessment (98.4% to 94.4%) that was also significant. For the five palpation components, a significant improvement was made from pre to reassessment (3.4 to 4.5 average components used out of five), and retained from post- to reassessment (4.2 to 4.5).

For the silicone breast model examination, significant improvements were not made from pre to reassessment (59.8% to 60.5%) and significant decrease for post to reassessment (62.8% to 60.5%) for sensitivity. However, for specificity reassessment had the highest value and significant improvements were made in the pre to reassessment (20.6% to 49.4%) and post to reassessment (32.3% to 49.4%) comparisons for specificity.

TASK 15 (Year2 only): Assess implementation of CRGS

- Convene focus groups at each site.
- Identify local implementation issues.
- Identify global implementation issues.
- Compare and contrast themes across sites.

Dates for reassessment Assessment of these variables occurred during the reassessment visits (schedule described in Task 13). Focus groups of 10-15 physicians in each group were convened to assess the implementation of the CRGS. Dr. Barbara Given, an experienced focus group facilitator has agreed to lead all of the Focus Groups.

Questions asked during these sessions are outlined below:

Focus Group Questions:

1. Relevance of the curriculum to your daily practice
 - How have you used the information on BCS and follow-up workshop to help your patients?
2. Impact on your professional effectiveness in breast cancer screening and follow-up of abnormalities. Related to performing comprehensive breast exams now a year later:
 - What has been your experience in your ability to continue to perform comprehensive breast exams?
 - How have you altered your examination since the training session?
 - How did the teaching workshop help you in the breast cancer-screening component of patient care this past year?
 - How did the teaching workshop assist you in follow-up of breast disorders for your patient care this past year? (Give an example related to direct care).
3. Value of the Clinical Skills Component
 - How has the training assisted you in breast examination? Be specific to:
 - position of patient during exam
 - skin exam
 - lump identification (number & type)
 - communication with the patients
4. Barriers in applying the content learned in daily practice.
 - How do practice realities and time pressure help or interfere with your ability to carry out techniques learned in the workshop?
5. Utilizing the Chart Reminder/Guideline System for screening and follow-up of breast abnormalities
 - How did you utilize the Chart Reminder/Guideline System? How did it help you in your daily practice?
6. Relating to the use of the Gail model:
 - How have you been able to use the Gail model in the actual care of your patients?
 - What would you recommend about training to make Gail model beneficial to your care?
7. Overall, how has your practice for CBE changed due to this training?
8. What was the most valuable component of the course as you review it now, one year later?
9. Additional needs/topics that could be covered during this Workshop or in future educational offerings.
- 10 Suggestions for improving the workshop.**

RESULTS:

Appendix 23 has a complete listing of the Focus Group results. The overall impression as to the relevance of the curriculum to daily practice of the participants was that after the training, physicians felt more confident with performing the clinical breast exams, some learned for the first time the appropriate CBE technique and changed the way in which they documented their findings. Over 80% found the curriculum very useful as a reference for appropriate follow-up of abnormalities detected and reported using the Guidelines that were inserted into the charts. This provides documentation that this curriculum impacted the standard of practice for breast care. For each question asked during the focus groups detailed information is provided in Appendix 23.

TASK 16 (Year2 only): Hire and train nurse auditors for the post-intervention chart audit.

Hire nurse abstractors at each site (9 sites): Six nurses returned for a second year of abstracting. Ten additional nurses were hired and trained to complete the abstracting. With the exception of one individual, all individuals hired were at least an R.N., with many being bachelor and master prepared. Many had experience with abstracting.

Bring all new nurse abstractors to MSU for a two day training workshop: On October 16 and 17, 2000, a nurse abstractor training was held on the campus of Michigan State University. Ten nurses were trained to abstract data related to breast care at the nine residency program sites. The training was again led by Barbara Given, Ph.D., R.N., with assistance from Suiying Huang, Data Coordinator, and Jodi Holtrop, Ph.D., Project Manager. Please see **Appendix 5** for the agenda and instruction manual for this two day training. The training followed the same format and content as that for year one. Upon completion of the training, the nurses were given practice cases to complete and return. Auditors revised these practice cases until she achieved a Kappa of 90% or higher as a measure of inter-rater agreement for the various components of the chart audit. Again, this educational process and quality control assessment took additional time and delayed the beginning of the auditing process by approximately three to four weeks. Returning nurses were trained during a one-day refresher training held on September 28, 2000 and October 23rd (two separate trainings as we were unable to schedule a day when all returning nurses were available). Nurses were given one practice case to complete correctly and allowed to begin after proper completion of this case. Due to the attrition of several nurses from the study, two additional nurses were trained in a one-day training on January 17, 2001.

Once implemented, the auditors provided weekly reports on their progress. Email and telephone were used to deal with problems daily as they arose.

The control site residency programs did not select to utilize the CRGS, and only one intervention site (Saginaw) chose to continue the CRGS insertion for all new eligible patients. All Intervention sites were given a stamp that said "MSU DoD Research Grant July 1999-October 2000" and the CRGS materials in the charts were stamped by the nurse abstractors so the health care providers understand that this was a specific research project, and they hopefully will continue to use the guidelines provided in the charts, but it was no longer to be evaluated formally.

TASK 17 (Year2 only): Post-intervention chart audit (8/1/99-7/31/2000)

A list of names of patients whose charts were eligible for audit was generated in October, 2000. Auditors began abstracting data in November, 2000. The table below lists the residency program sites, and an approximate number of records audited and progress with completion. It is important to note that the first column (# eligible) is often inflated. The data analysis systems at various residency sites are highly variable and in some locations, the accuracy of the list to reflect the truly eligible patient population is lacking. Thus, at several sites, such as Saginaw, McLaren, and Providence, the true number of patient charts to be abstracted is less than what is reflected here.

<u>Intervention sites:</u>	<u># Eligible</u>	<u>Date completed</u>	<u># of charts abstracted</u>
Kalamazoo Center for Medical Studies	1250	March, 2001	1228
MidMichigan Regional Medical Center, Midland	2300	April , 2001	2237
Saginaw Cooperative Hospitals, Inc.	1500	June, 2001	1500
Sparrow/MSU – St. Lawrence site	960	March, 2001	953
Sparrow/MSU – Sparrow and Mason site	2250	April, 2001	1475

<u>Control sites:</u>	<u># Eligible:</u>	Date completed	# of charts abstracted
Genesys Health Systems, Flint	1340	May, 2001	1277
McLaren Regional Medical Center, Flint	900	May, 2001	765
Munson Medical Center, Traverse City	1200	June, 2001	1167
Providence Hospital, Southfield	2000	June, 2001	2036

TASK 18 (Year2 only): Quality control of the post-intervention chart audit at each practice site.

During the second year of data abstracting, two quality control evaluations were performed. Two of the abstractors were hired to also perform quality assurance checks. They performed quality control on each other charts to check for accuracy.

Dorota Mikucki and Tara Johnson audited the same selected records as had been completed by the nurse auditors at a given site. Suiying Huang, Data Manager, then completed Kappa tests for the charts audited for the purpose of quality control.(**Appendix 18**).

December 15, 2000 and January 15, and April 12, 2001 - St. Lawrence, Lansing

December 18, 2000 and February 21, 2001 – Sparrow, Lansing

January 12, and April 3, 2001 – Kalamazoo

January 15 and March 26, 2001 – Genesys, Flint

January 19, and April 26, 2001 – McLaren, Flint

January 29, and April 2, 2001 – Midland

February 12, March 21, April 10, and April 18, 2001 – Providence, Southfield

February 5, and March 27, 2001 – Saginaw

February 19, and April 23, 2001 – Traverse City

During the quality assurance checks, 12 records were randomly selected from each auditor's patient eligibility list. Charts were first sorted on their eligibility code 1, 2, or 3. Within the eligibility code of 1, charts were sorted on the number of breast care encounters. The distribution of the 12 charts chosen for quality control audit was as follows: 2 with Ecode=3; 2 with Ecode=2, and 8 with Ecode=1. Within the 8 charts with Ecode=1, 2 charts had 0 encounter, 2 had 1 encounters, 2 had 2 encounters, 1 had 3 encounters and 1 had 4 encounters or more

The quality assurance auditor audited the same selected records as had been completed by each auditor. Suiying Huang, Data Manager, then completed Kappa tests for the charts audited by both the nurse abstractor and quality assurance abstractor (**Appendix 18 year two**).

RESULTS:

The Year Two section of Appendix 18 lists the complete results of the quality assurance checks for the year two of the project. The "*" in the tables specifies that Kappa value was 100%. Over 90% of Kappa values were 100% and the remaining ones were either excellent (>80%) or Very Good (60-80%) Only 4 kappa values were less then 60% and they were 58.9%, 56.2%, 46%, and 38%. We conducted two initial quality controls with abstractor 61. Her kappa for the first quality control was unacceptably low. Therefore we gave her further instructions about abstraction and asked her to go back and review all the charts she abstracted prior to her first quality control. The kappa results shown here are calculated based on the second quality control. Nurse abstractor 71's kappa result for Immediate Mammo (see table for kappa results from Form-IV, followup-form) was 38%. She was asked to review all her charts and correct on this particular variable. We attribute this high quality of abstracting to the intensive training that the abstractors received, the requirements by Dr. Given that for the 10 practice cases their Kappa values be at least 90% prior to being allowed to abstract in the field.

TASK 19 (Year2 only): Data entry and analysis of the post-intervention chart audit

- Data entry
- Data analysis of pre-post intervention changes in the outcome measures defined in hypotheses 1a-1f

Chart auditing is finished in all but 2 sites (Traverse City and Providence). It is anticipated that the remaining two sites will be finished within the next week. Analysis of these results will begin in June and continue until completed (expected to be completed by late Fall, 2001).

TASK 20 (Year2 only): Manuscript preparation

In progress.

Abstracts and presentations are provided in section "REPORTABLE OUTCOMES."

*Improved Follow-up of Breast Abnormalities Through
Comprehensive Breast Care in Women 40 to 70 Years of Age*

KEY RESEARCH ACCOMPLISHMENTS

- Development of a highly effective, comprehensive curriculum addressing the epidemiology, screening and work-up and follow-up of breast abnormalities.
- Design of a workshop to teach and assess the following:
 - knowledge of essentials of breast care
 - risk assessment using the Gail model
 - skills related to CBE technique
 - skills related to ability to detect lumps in silicone breast models.
- Design and implement a comprehensive method of chart abstraction that can be entered directly into the database on a laptop. The database was developed specifically for this project.
- Design and implement Workshop for teaching nurse auditors how to perform chart audits according to well-established guidelines that incorporated quality control assessment.
- Establishment of Community relations among the 8 community Residency programs (11 sites) that generated enthusiasm and cooperation for this and further research endeavors.
- Impacted the knowledge and the clinical breast exam skills of Workshop participants as evidenced by improved scores on knowledge test, CBE techniques in live patient models, and improved sensitivity and specificity for lump detection in silicone breast models on the day of the Workshop.
- One year later, reassessment of these skills demonstrated retention of most of these components mentioned at a level above that of the pre-test but below immediate post-test levels on the day of the Workshop.
- Screening rates have been calculated for 11 different practice sites and indicate unacceptably low rates for performance of CBE and screening mammography in both 40-49 and ≥ 50 years old women, pointing to the need for further interventions if we are to achieve the Healthy People 2000 goals with regard to breast cancer screening. Analysis to be done this year will assess the impact of the current Workshop on breast cancer screening rates.
- The translatability of this work has already begun.
 - The physician curriculum has been revised to be applicable to Nurse Practitioners. Dr. Barbara Given was funded by the State of Michigan on a grant entitled: *"Improving the Quality of Breast Cancer Screening: Education for Nurse Practitioners"*.
 - Also, the current curriculum is under revision to make it applicable to Family Practice physicians in Poland. Drs. Osuch and Pathak will travel to Poland in August to discuss further collaboration and possibility of bringing a group of Polish physicians to US for "training the trainer" Workshop. These individuals will then be expected to organize and conduct similar Workshops in Poland.
- Several abstracts and posters have been either accepted for upcoming meetings for presentation or have already been presented. Two graduate assistants have worked on this project. One has completed her Master's Thesis based on the data collected (copy enclosed in Appendix 24), and the other is writing a manuscript evaluating the impact of different ways of calculating sensitivity for lump detection in silicone breast models. Both students have submitted abstracts and been accepted for Poster presentations at the meeting: Congress of Epidemiology 2001, June 14-16, Toronto, Ontario, Canada.

*Improved Follow-up of Breast Abnormalities Through
Comprehensive Breast Care in Women 40 to 70 Years of Age*

REPORTABLE OUTCOMES

Abstracts and Other work

The following abstracts were submitted and accepted for presentations at conferences. Additionally we include Master's Thesis that resulted from this work, as well as a Please see **Appendix 24** for a copy of the abstracts.

Teaching Clinical Breast Examination: Pre-Post Evaluation. Pathak, D., Osuch, J., Barry, H., Zuber, T., Holtrop, J., Given, B., Swanson, GM.. Presented at "Era of Hope" meetings, June8-12, 2000, Atlanta, Georgia.

Clinical Breast Examination, Can We Be More Specific? MR Brennan, HC Barry, DR Pathak, JR Osuch and PK Pathak. To be presented at the meeting: Congress of Epidemiology 2001, June 14-16, 2001 Toronto, Ontario, Canada.

Breast Cancer Screening in Three Michigan Family Practice Clinics. Huang, S., Osuch, J., Given, B., Barry, H., Holtrop, J., Swanson, M., Pathak, D. To be presented at the meeting: Congress of Epidemiology 2001, June 14-16, 2001 Toronto, Ontario, Canada.

Breast Cancer Screening in Three Michigan Family Practice Clinics. Huang, S., Master's Thesis. Department of Epidemiology, Michigan State University, May, 2001.

Improving the Quality of Breast Cancer Screening: Education for Nurse Practitioners.. Current curriculum was revised for Nurse Practitioners. The project was funded by the State of Michigan Cancer Control Grant. Dr. Barbara Given P.I.

Papers in Progress

Grading the clinical breast exam, can we be more specific? Michael R. Brennan, Henry C. Barry, Pramod K. Pathak, Janet R. Osuch, Dorothy R. Pathak.

Breast Cancer Screening in Nine Michigan Family Practice Clinics. Suiying Huang, Janet R. Osuch, Barbara Given, Henry C. Barry, Jodi Holtrop, Maria Swanson, Dorothy Pathak.

Training and Use of Patient Instructors for Clinical Breast Examination Teaching. Holtrop, J., Barry, H., Pathak, D..

*Improved Follow-up of Breast Abnormalities Through
Comprehensive Breast Care in Women 40 to 70 Years of Age*

CONCLUSIONS

We have successfully implemented a curriculum that was specifically developed for this project, entitled "ESSENTIALS OF BREAST CARE." We have evaluated its short-term efficacy in 10 Residency sites and found that cognitive (knowledge, attitudes and behaviors) and clinical (CBE technique, ability to detect lumps in silicone breast models) skills are improved. Last year, we have submitted an abstract to the Era of Hope meetings, (June, 2000, Atlanta, Georgia), with the results of the immediate effect of the curriculum on cognitive and clinical skills in five intervention sites. This year we have submitted two abstracts that were accepted at the meetings: Congress of Epidemiology 2001, held in Toronto June 14-16, 2001. One of the abstracts is the result of the work that was initiated last year to evaluate the influence of different criteria for defining true and false positives in calculations of sensitivity and specificity of clinical breast examination when a known gold standard exists. A paper is also in progress. The second abstract addresses the breast cancer screening rates for three family practice residency clinics in Michigan.

Drs. Osuch and Pathak are continuing to review charts identified with abnormal findings from both Year 1 and Year 2 abstracting periods. These charts constitute about 10% of all charts abstracted. Each abnormality needs to be reviewed manually, and the follow-up judged as appropriate or inappropriate according to the algorithms developed for the curriculum. In all cases where management is judged inappropriate, and in any equivocal cases where judgment could be swayed, the charts are discussed in a team meeting with all of the investigators involved in clinical care so that a consensus judgment can be made. Breast cancer screening rates have been calculated for baseline year for all sites, and point to two important observations: (1) the current breast cancer screening rates for CBE and mammography individually or combined are unacceptably low, (2) when screening is recommended, (comparison of ordered vs. done) compliance with the recommendation is above 98% and accomplished 90% of the time within 3 months. To meet the Healthy People 2000 recommended mammography and CBE combined screening rate of 60%, interventions to improve these findings at FPC will be urgently needed.

One unexpected outcome of this grant was that we have been asked to provide the "ESSENTIALS OF BREAST CARE" curriculum to other health care professionals (Nurse Practitioners, Ob/Gyn residents, etc.). A one-year project to train Nurse Practitioners (10/1/2000-9/30/2001) has been funded by the State of Michigan, and is currently ongoing. A summary entitled: "Improving the Quality of Breast Cancer Screening: Education for Nurse Practitioners" is included in Appendix 24.

The design of this study offered the curriculum to the control sites during the second year. The informal communication among Residency Directors combined with a perceived need for this training resulted in all Control Sites participating in the Workshop. These Workshops were delivered in the Fall 2000.

We have requested one year extension since abstracting of charts in the second year was delayed by 3 months, due to our own realization that we need 15 month time period post intervention in order to calculate screening rates comparable to those for baseline year. In the timetable we provide the description of tasks and projected time to completion. We expect successful completion of the project according to the scope of work statement in the original grant, by the end of the extension year, i.e., February 2002.

*Improved Follow-up of Breast Abnormalities Through
Comprehensive Breast Care in Women 40 to 70 Years of Age*

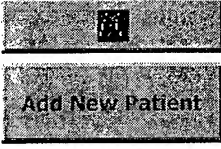

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APPENDIX 1

Chart Audit/Database Form

Form I- Front-End Form

	Patient Name (Last):	testing
	(First):	testing
	Medical Record Number:	
	Date Of Birth:	
	Abstractor's ID:	

Eligibility Criteria: Check One Item For Each Statement (1-5)

1. Patient gender is:
2. Patient has been seen in last three years
2a. Date of the very first visit to the FPC provider:
3. Patient birthday is between August 1, 1928 and July 31, 1960
4. Breast health care provided by
5. Active patient between 8/1/99 - 7/31/00
5a. If there is documentation patient left practice before 7/31/00
Other, specify:
Date of Documentation:

Please remember to enter
information 2a. Use and stamp
the guideline and summary
sheet

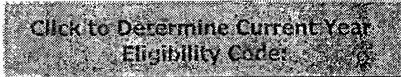
Meaning of Eligibility Code:

For site number 1-5:

- 1= Eligible for abstract and insertion
- 2= Eligible for insertion only
- 3= Ineligible

For site number 6-9:

- 1= Eligible for abstract
- 2 or 3= Ineligible





For your reference, this is the old
ECoded assigned last year



Rules for Assigning Study ID:

Study ID will remain the same for all patients who are a part of last year's abstracted data . However, you will be required to specify their Eligibility code for the current year. Even if the Eligibility code for the current year changes, the Study ID remains the same. Your decision whether to proceed with abstraction for the current year will depend on the current ECode.

For patients who don't have a record in last year's database, please assign study ID according to the rules specified below

Study ID is a 6-digit number. The first digit is your site number. The second digit is the Eligibility code shown in the box above. The rest four digits are consecutive numbers starting 0001.

To assign study ID, please look in the box on the right, find out what was the last number assigned for that specific eligibility category, and use the next consecutive number.

For eligibility code =	911323
For eligibility code =	920825
For eligibility code =	930472

STUDY ID:

1

Today's Date:

3/19/01



FOR INTERVENTION SITES (SITE NUMBER 1-5) ONLY:

For patients with Ecode = 1 or 2 only: please check if additional information was written on the Summary of Breast Care Sheet (one white sheet which can be found together with the guideline insertion) .

- ☐ Guideline Inserted ☐ Guideline Not Found
☐ Summary Sheet Inserted ☐ Summary Sheet Not Found
☐ Additional Information on Summary Shee
☐ No Additional Information on Summary Shee

HAVE YOU STAMPED GUIDELINES AND SUMMARY SHEET?

Click here To
Continue

Search / Add New Patient

Chart Review Form (Only for Eligible Patient)

Study ID:

1. Date of Most Recent Office Visit Between 8/1/99 to 7/31/00 (MM/DD/YY):

2. Autocalculated Date For the Last Eligible Visit Within the Last 15 months (MM/DD/YY):

2a. Overlap Period

2b. Last Year's Autocalculated Date For the Last Eligible Visit Within the Last 15 months:

3. Total Number of Visits Within 15 Months, Including The Most Recent Visit:

4. Was A Breast Care Performed During Any of The Visits Within The 15 Months Period:

5. Personal/Family History Of Breast Cancer?

Search / Add New Patient

Rule for filling in the age at diagnosis:

- 1) Fill in exact age when information is available;
- 2) Fill in '777' if only known Pre-menopausal equal to or less than 50 years of
- 3) Fill in '888' if only known Post-menopausal or greater than 50 years old;
- 4) Fill in '999' if no information is available.

In Self?

No

Age:

Surgery/Reconstruction:

- ☐ Complete Breast Removal ☐ Partial Breast Removal/Lumpectomy
☐ Prophylactic Implants ☐ Autologous Reconstitution
☐ Other, specify _____
☐ Undocumented

Treatments (check all that apply)

- ☐ Chemotherapy ☐ Radiation ☐ Tamoxifen/Nolvadex
☐ Alternative medicine(s), specify _____
☐ Other, specify _____
☐ Undocumented

In Mother?

No

Age:

In Sister?

No

☐ Sister1

Age:

☐ Sister2

Age:

In Daughter?

No

☐ Daughter1

Age:

☐ Daughter2

Age:

In Other Relatives?

No

Please specify:

BOX-A

Record information for patient's each visit when a breast care was performed. Start with the first visit when any breast care activity was recorded during that 15 months period. Click the button on the right to continue.

Continue to
record visit info

Go To First Patient

Go To Previous Patient

Go To Next Patient

Go To Last Patient

(Click Any of the Buttons Above to Navigate the Record)

Form II- Visit Entry

Add New Visit

Go To First Visit

Go To Previous Visit

Go To Next Visit

Go To Last Visit



Study ID:

110005

Last Eligible Visit:

Go Back to Front-End

Please fill out Question 6 and Question 7 for every visit/call.

6. Date of Breast Care Activity Was Recorded: 9/28/98

Type of Contact:

If this visit is about a test result, you can directly go to Test Result Form, without filling out CBE documentation

7. Purpose of this Visit/Call:

Specify:

Go Directly to
Test Result Form

8. Who Performed Breast Care/Phone Consultation? (Check All That Apply)

☐ Resident Physician ☐ Faculty Physician ☐ Physician Assistant ☐ Nurse Practitioner ☐ Undocumented

Breast Care Provider1:

Breast Care Provider2:

9. Patient Presenting Symptoms/Signs (Check All That Apply)

Which breast(s) has presenting symptom?

If you don't know which breast, please record information in "Left Breast" category.

Left Breast:

Right Breast:

☐ None ☐ Undocumented/Don't know

☐ Lump(s)/Mass(es)/Asymmetrical thickening

☐ Nipple Discharge

☐ Skin/Nipple change (check all that apply)

☐ Skin Dimpling ☐ Erythema/Skin thickening

☐ Nipple Retraction ☐ Nipple Scaling

☐ Pain/Tenderness

☐ Occult Mammographic Abnormality

☐ Density(Nodule or Asymmetry)

☐ Microcalcifications

☐ Other, specify:

☐ None ☐ Undocumented/Don't know

☐ Lump(s)/Mass(es)/Asymmetrical thickening

☐ Nipple Discharge

☐ Skin/Nipple change (check all that apply)

☐ Skin Dimpling ☐ Erythema/Skin thickening

☐ Nipple Retraction ☐ Nipple Scaling

☐ Pain/Tenderness

☐ Occult Mammographic Abnormality

☐ Density(Nodule or Asymmetry)

☐ Microcalcifications

☐ Other, specify:

10. CBE Documentation:

11. CBE Findings (Check All That Apply):

☐ **Bilateral Implants**

☐ **Mastectomy, which breast?**

☒ **Previous abnormality resolved**

☐ Lump/mass resolved ☐ Observational finding resolved ☐ Nipple discharge resolved ☐ Pain gone

☐ **Normal/Symmetrical nodularity/Symmetrical fibrocystic (Fill Out Quality of CBE Documentation)**

Quality of Written Description of CBE Documentation (Check All That Apply):

<input type="checkbox"/> Inspection, specify:	Nipple Change	Undocumented	Breast Size/Shape	Undocumented
	Scar	Undocumented	Skin Change	Undocumented
<input type="checkbox"/> Palpation, specify:	Fibrocystic Breast	Undocumented	Nodularity	Undocumented
	Mass(es)	Undocumented	Pain/tenderness	Undocumented
	Mastectomy site(s) free of masses Undocumented			
<input type="checkbox"/> Lymph node examination	Adenopathy/Axillary Nodes Undocumented			
<input type="checkbox"/> No specific documentation besides normal				
<input type="checkbox"/> Other, Specify:				

Abnormal: Which breast(s) has abnormal finding?

If you don't know which breast, please record information in "Left Breast" category.

Left Breast:

Right Breast:

Location:

Location:

☒ Lump(s)/Mass(es)/Asymmetric breast thickening/
Asymmetric Fibrocystic

Lump size:

Depth:

Hardness:

Mobility:

Shape:

Texture:

Additional Findings With Lumps (check all that apply):

Skin Dimpling/Retraction Undocumented

Skin Erythema Undocumented

Skin Peau d'orange or
Skin Thickening Undocumented

Nipple Retraction Undocumented

Nipple Scaling Undocumented

Pain/Tenderness Undocumented

Fibrocystic Breast(s) Undocumented

Nipple Discharge Undocumented

☐ Other, Specify:

☐ Nipple Discharge With No Lump

Spontaneous?

Color

Unilateral or bilateral?

Single or multiple ducts?

☒ Observational Findings With No Lump

☐ Skin dimpling/retraction

☐ Skin Erythema

☐ Skin Peau d'orange/Skin Thickening

☐ Nipple retraction

☐ Nipple scaling

☒ Pain

☐ Breast pain

☐ Chest wall pain

☐ Unspecified

☐ Other, specify:

☐ Lump(s)/mass(es)/Asymmetric breast thickening/
Asymmetric Fibrocystic

Lump size:

Depth:

Hardness:

Mobility:

Shape:

Texture:

Additional Findings With Lumps (check all that apply):

Skin Dimpling/Retraction Undocumented

Skin Erythema Undocumented

Skin Peau d'orange or
Skin Thickening Undocumented

Nipple Retraction Undocumented

Nipple Scaling Undocumented

Pain/Tenderness Undocumented

Fibrocystic Breast(s) Undocumented

Nipple Discharge Undocumented

☐ Other, Specify:

☐ Nipple Discharge With No Lump

Spontaneous?

Color

Unilateral or bilateral?

Single or multiple ducts?

☒ Observational Findings With No Lump

☐ Skin dimpling/retraction

☐ Skin Erythema

☐ Skin Peau d'orange/Skin Thickening

☐ Nipple retraction

☐ Nipple scaling

☒ Pain

☐ Breast pain

☐ Chest wall pain

☐ Unspecified

☐ Other, specify:

Quality of Written Description of CBE Documentation For Abnormal Findings (Check All That Apply):

Drawing of abnormal findings				
Inspection, specify:	Nipple Change	Undocumented	Breast Size/Shape	Undocumented
	Scar	Undocumented	Skin Change	Undocumented
Palpation, specify:	Fibrocystic Breast	Undocumented	Nodularity	Undocumented
	Mass(es)	Undocumented	Pain/tenderness	
Lymph node examination				
Adenopathy/Axillary Nodes		Undocumented	Lymph Node Enlarged?	
Other, Specify:				

☐ Click here if you changed anything about this visit entry, compared to last year's entry and briefly specify the changes

**Go To Followup
Form**

**Go To Test
Result Form**

Form III-Test Result Entry

110005

Date of the Visit: 9/22/98

Last Eligible Visit:

12. Mammogram Documentation:

1. Ordered/Recommended/Encouraged	Date:
2. Mammogram Performed	Date:
3. Results Obtained	Stamped/Documented? Date:
4. Results Reviewed By FPCP	Signed/Documented? Date:

13a. Mammogram Findings: Final Impressions Which Breast?

If you don't know which breast, please record information in "Left Breast" category.

Left Breast:

Right Breast:

<input type="checkbox"/> Normal/No Finding Identified/Category I <input type="checkbox"/> Normal/Benign-appearing abnormality/Category II Probably benign/possibly malignant, indeterminate /Category III <input type="checkbox"/> Suspicious for malignancy/Category IV <input type="checkbox"/> Malignant until proven otherwise/Category V <input type="checkbox"/> Other: Specify:	<input type="checkbox"/> Normal/No Finding Identified/Category I <input type="checkbox"/> Normal/Benign-appearing abnormality/Category II Probably benign/possibly malignant, indeterminate /Category III <input type="checkbox"/> Suspicious for malignancy/Category IV <input type="checkbox"/> Malignant until proven otherwise/Category V <input type="checkbox"/> Other: Specify:
---	---

13b. Mammogram Findings: Description Which Breast?

If you don't know which breast, please record information in "Left Breast" category.

Left Breast:

Right Breast:

☐ Asymmetric Breast: more in which breast

<input type="checkbox"/> Bilateral Implants <input type="checkbox"/> Radiolucent Breasts <input type="checkbox"/> Dense Breasts/Dense Nodular Breasts <input type="checkbox"/> Rounded density(ies), most likely cyst or fibroadenoma <input type="checkbox"/> Irregular Density(ies) <input type="checkbox"/> Benign Appearing Calcifications <input type="checkbox"/> Suspicious Calcification <input type="checkbox"/> Calcified Fibroadenomas <input type="checkbox"/> Axillary Lymph Nodes <input type="checkbox"/> Other, specify:	<input type="checkbox"/> Bilateral Implants <input type="checkbox"/> Radiolucent Breasts <input type="checkbox"/> Dense Breasts/Dense Nodular Breasts <input type="checkbox"/> Rounded densities, most likely cyst or fibroadenoma <input type="checkbox"/> Irregular Density(ies) <input type="checkbox"/> Benign Appearing Calcifications <input type="checkbox"/> Suspicious Calcification <input type="checkbox"/> Calcified Fibroadenomas <input type="checkbox"/> Axillary Lymph Nodes <input type="checkbox"/> Other, specify:
---	--

13c. Mammogram Findings: Location For Category II and Up

Which Breast?

If you don't know which breast, please record information in "Left Breast" category.

If NOT SPECIFIED, check SCATTER/THROUGHOUT Breast category

Left Breast Location:**Right Breast Location:**

<input type="checkbox"/> Upper Outer Quadrant	<input type="checkbox"/> Lower Outer Quadrant	<input type="checkbox"/> Upper Outer Quadrant	<input type="checkbox"/> Lower Outer Quadrant
<input type="checkbox"/> Upper Inner Quadrant	<input type="checkbox"/> Lower Inner Quadrant	<input type="checkbox"/> Upper Inner Quadrant	<input type="checkbox"/> Lower Inner Quadrant
<input type="checkbox"/> Lateral Breast		<input type="checkbox"/> Lateral Breast	
<input type="checkbox"/> Medial Breast		<input type="checkbox"/> Medial Breast	
<input type="checkbox"/> Areolar/Nipple Area		<input type="checkbox"/> Areolar/Nipple Area	
<input type="checkbox"/> Deep Against Chest Wall		<input type="checkbox"/> Deep Against Chest Wall	
<input type="checkbox"/> Scattered/Throughout Breast		<input type="checkbox"/> Scattered/Throughout Breast	
<input type="checkbox"/> Other, specify: _____		<input type="checkbox"/> Other, specify: _____	

14. Patient Notified of the Mammogram Findings?

Date of Notification:

15. Cyst-Fine Needle Aspiration (FNA)

Done by: _____

Date done: _____

☐ Mass resolved/fluid not bloody ☐ Fluid bloody☐ Residual Mass☐ Other, specify: _____☐ Sent Fluid to Cytology

Results Obtained

Stamped/Documented?

Date: _____

Results Reviewed By FPCP

Signed/Documented?

Date: _____

Cytology Results:☐ Insufficient/Hypocellular/Apocrine Cells☐ Benign/Fibrocystic/Apocrine Cells☐ Atypical cells☐ Suspicious for malignancy☐ Malignant☐ Other, specify: _____**16. Patient Notified of the FNA Findings From Cytology?**

Date of Notification: _____

17. Solid Mass-Fine Needle Aspiration Biopsy (FNAB)

Done by: _____

Date done: _____

☐ Specimen Submitted For Analysis

Results Obtained

Stamped/Documented?

Date: _____

Results Reviewed By FPCP

Signed/Documented?

Date: _____

Pathology Results:☐ Insufficient/Hypocellular☐ Benign/Fibrocystic☐ Atypical cells☐ Suspicious for malignancy☐ Malignant☐ Other, specify: _____**18. Patient Notified of the FNAB Findings From Path Report?**

Date of Notification: _____

19. Ultrasound Findings:**Ordered by:****Date done:**

Results Obtained

Stamped/Documented?

Date:

Results Reviewed By FPCP

Signed/Documented?

Date:

☐ Negative finding☐ Simple cyst(s)☐ Solid mass(es) or complex cyst(s)☐ Other, specify:**20. Patient Notified of the Ultrasound Findings?**

Date of Notification:

21. Image-Guided Biopsy/Open Biopsy Results: Date done:

Results Received

Stamped/Documented?

Date:

Results Reviewed By FPCP

Signed/Documented?

Date:

Open Biopsy Findings(check all that apply):☐ Benign/No Evidence of Malignancy☐ Ductal Carcinoma in situ☐ Benign/Fibrocystic Changes☐ Lobular Carcinoma in situ☐ Benign/Fat Necrosis☐ Atypical Hyperplasia☐ Benign/Lipoma☐ Invasive Ductal Carcinoma☐ Benign/Fibroadenoma☐ Invasive Lobular Carcinoma☐ Other, specify:

☐ Click here if you changed anything about this visit entry, compared to last year's entry and briefly specify the changes

Go Back to Visit Form**Go To Followup Form**

Form IV-Follow-up Entry

ProVID: [REDACTED]

100005

Date of Visit: [REDACTED]

9/27/98

Last Eligible Visit: [REDACTED]

23. Recommended Follow-Up(s) (Check All That Apply)

☐ **Undocumented**

(Low-risk for Normal CBE and Mammogram (or One of Them Undocumented):

☐ Routine Screening ☐ 12 Month CBE ☐ 12 Month Mammogram

☐ Following ACS Guidelines ☐ Following Other Guidelines specify: _____

Recommended by: _____

Comments: _____

Specific Abnormalities:

Breast Mass/Asymmetry Initial Approach:

- ☐ CBE at better phase cycle (3-10 days)
- ☐ Fine Needle Aspiration for Cyst

If Known Breast Cyst:

- ☐ Send Fluid to Cytology ☐ Reaspiration
- ☐ (How many) month CBE

If Known Solid Mass:

- ☐ Fine Needle Aspiration Biopsy
- ☐ Specimen Submitted for Analysis
- ☐ Repeat aspiration
- ☐ Clinical Followup Every 3 Months for 1 Year

For Nipple Discharge:

- ☐ Endocrine work-up

For Skin/Nipple Changes on Observation:

- ☐ 2 weeks antibiotics ☐ Skin Biopsy
- ☐ 2 weeks topical hydrocortisone

For Breast pain:

- ☐ Eliminate Caffeine
- ☐ Adjust Estrogen Dose
- ☐ Local Anesthetic Injection
- ☐ Primrose Oil, How Many Months?
- ☐ Reassurance and CBE within 3-6 months if pain persists
- ☐ Supportive Brassiere
- ☐ Over-the-counter Analgesics
- ☐ Danazol, Bromocriptine

For Occult Mammographic Abnormality:

- ☐ Radiologic Biopsy/Image-Guided Biopsy

Recommended by: _____

Follow-up Common To Any Abnormalities:

☐ Call if Problem Worsens

☐ Routine Screening

Recom. by: _____

Immediate Mammogram Workup:

- ☐ Regular Mammogram
- ☐ Extra Mammogram Views
- ☐ Cone or Spot Compression
- ☐ Magnification Views

Recom. by: _____

Interval Followup:

(How many) month mammo

(How many) month CBE

Recom. by: _____

☐ Ultrasound

Recom. by: _____

☐ Surgical Referral

Recom. by: _____

☐ Undocumented

**Other Recommendations Or Comments
Concerning Abnormality(ies):**

General Comments About This Visit:

Assessment/Recommended Follow-up From Surgeon's Letter

1. Letter Written	Date:	
2. Letter Received	Stamped/Documented?	Date:
3. Letter Reviewed by FPCP	Signed/Documented?	Date:

Assessment

- ☐ Referral Diagnosis Not Confirmed
- ☐ Referral Diagnosis Confirmed
- ☐ Additional/New findings
- ☐ Further Tests Recommended/Done By Surgeon, check all that apply
 - ☐ Immediate Mammogra
 - ☐ Interval Mammogram, how long
 - ☐ Interval CBE, how long?
 - ☐ Ultrasound
 - ☐ FNA
 - ☐ FNAB
 - ☐ Radiological/Image Guided Biopsy
 - ☐ Open Biopsy
- Evidence of Malignancy?
- ☐ Previous Abnormality Resolved
- ☐ Current Abnormality Resolved
- ☐ Other Comments From Surgeon's Lette

Followup

- ☐ No Further Workup Required
- ☐ Followup In Primary Care Office
- ☐ Followup In Surgeon's Office

☐ Click here if you changed anything about this visit entry, compared to last year's entry and briefly specify the changes

**Go Back to
Form II**

**Go Back to
Form III**

**Add New
Visit**

**Search/
Add New**

APPENDIX 2

Essentials of Breast Care for Primary Care Physicians Curriculum Manual (separately bound)



ESSENTIALS OF BREAST CARE

PARTICIPANT MANUAL

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*This curriculum was written as part of a grant funded by the United States Department of Defense (#DAMD17-98-1-8118) entitled "*Improved Follow-up of Breast Abnormalities through Comprehensive Breast Care in Women 40 to 70 Years of Age.*"

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ESSENTIALS OF BREAST CARE

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ACCREDITATION STATEMENT - CONTINUING MEDICAL EDUCATION

Michigan State University College of Human Medicine is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians. MSU-CHM designates this continuing medical education activity for up to 8 credit hours in Category I, or the Physician's Recognition Award of the American Medical Association.

CONFLICT OF INTEREST STATEMENT

None of the authors of the *Essentials of Breast Care* curriculum has any financial interest in any aspect of breast care screening, diagnosis or treatment addressed in this curriculum.

HISTORY OF THE CURRICULUM

This curriculum has been developed through the efforts of numerous people and over the life of many grants. The current product represents major revisions in curricula and re-focuses on screening, counseling of high-risk women, essentials of clinical breast exam, and identification and work-up of abnormal findings.

The concept for the curriculum began when Michigan was named one of the first states to be funded for grant support for the federally legislated Breast and Cervical Cancer Screening Act administered by the Centers for Disease Control and Prevention in 1992. Janet Rose Osuch, M.D., then co-chair of the Breast Cancer Task Force at the Michigan Department of Public Health, was asked to prepare an eight-hour workshop for participants in the project throughout Michigan. Presented to physicians and nurse practitioners, this workshop focused on the screening and diagnosis of breast problems and taught a standardized approach to clinical breast exam using the MammaCare® models.

The American Medical Women's Association (AMWA) subsequently received grant support from the Centers for Disease Control to formalize the curriculum on breast care and to add a cervical cancer screening component. That project was completed in 1994 and subsequently sent by the Centers for Disease Control to each of the health departments across the country. AMWA had members of its women's health committee deliver the curriculum to the medical staff of several hospitals throughout the country.

Subsequently, the California Department of Health Services created its own curriculum on *The Essentials of Clinical Breast Examination*. Dr. Janet Rose Osuch served as one of the consultants on this project, which, along with other components, resulted in the production of the videotape on CBE that is used in the current curriculum.

In response to fiscal year 1996 legislation, the U.S. Assistant Secretary of Defense chartered a Tri-Service Interdisciplinary Team called the DoD Breast Cancer Work Group whose purpose is to provide direction and guidance to the Defense Health Program for breast cancer. The workgroup solicited proposals, and AMWA's breast component of the 1994 curriculum was chosen for delivery to physicians and primary care managers in the military system. The 1994 curriculum was expanded by Drs. Janet Osuch and Laura Morris to include genetics, treatment, and psychosocial issues. AMWA members were selected to attend a master training course and to deliver the curriculum to several dozen military sites world-wide in the Army, Navy and Air Force in 1997. The program was continued by military personnel who attended the master training course conducted by Laura Morris, MD through AMWA in fiscal year 1998.

The current project is part of a grant funded by the Department of Defense to evaluate whether physicians who attend the "Essentials of Breast Care" educational workshops will increase their rates of breast cancer screening and improve the appropriateness and timeliness of follow-up for abnormal findings.

ACKNOWLEDGEMENTS

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BIOGRAPHICAL SKETCHES

Dorothy R. Pathak, Ph.D., M.S.

Professor Pathak has been involved in epidemiological and bio-statistical research for the past 25 years, first at the University of New Mexico and now at Michigan State University. In both settings the principal focus of her work has been in studies of cancer etiology and prevention. After receiving her doctorate in bio-statistics Dr. Pathak served as a statistical consultant and co-investigator in a variety of research studies. In 1980 she was co-principal investigator on the "Cancer and Steroid Hormone Study" that evaluated the effect of oral contraceptives on breast cancer risk in pre-menopausal women.

In 1983 Dr. Pathak obtained a Master of Public Health degree in epidemiology from the Harvard School of Public Health. Her research at Harvard led to the publication of paper on the crossover effect of parity on breast cancer risk. Subsequent work includes paper on the effect of reproductive risk factors on breast cancer incidence in seven countries. Since that time Dr. Pathak has increasingly focused on the problem of breast cancer. Dr. Pathak's move to MSU in 1995 was undertaken in order to further her research on the effects of migration on breast cancer incidence among Polish immigrant women; therefore, proximity to the large Polish-American populations of Detroit and Chicago is an essential ingredient. In 1997 the study was funded by NCI and is currently ongoing both in Chicago and Detroit as well as in six sites in Poland.

At MSU she holds a tenured joint appointment with the Program in Epidemiology and the Department of Family Practice, and thus another principal research interest is the integration of epidemiological and preventive concepts into the practice of family medicine. Through her position in the Department of Family Practice Dr. Pathak is uniquely suited to lead this effort to improve compliance with recommendations for the secondary prevention of breast cancer.

Janet R. Osuch, M.D.

Dr. Osuch is a board certified surgeon with a fellowship in surgical oncology whose career has been dedicated to breast disease since 1987. She is one of the nation's premier figures in the fields of medical education and public policy on breast cancer and is a co-author of the AHCPR guidelines on the quality assurance of mammography.

Under a cooperative agreement with the Centers for Disease Control and Prevention (CDC) in 1994 and with the American Medical Women's Association (AMWA), Dr. Osuch developed a 200-slide educational module for primary care physicians covering breast cancer screening, clinical breast examination, and work-up of abnormal findings. This education module has been widely distributed by the CDC throughout the nation and was updated and delivered internationally through the Department of Defense in 1997 and 1998.

Dr. Osuch has served as a national spokesperson for breast cancer for the American Cancer Society, published several book chapters and journal articles related to breast disease, and has recently completed a master's degree in Epidemiology at Michigan State University. Her career is dedicated to the advancement of breast cancer knowledge through professional and public education.

Henry C. Barry, M.D., M.S.

Dr. Barry is the senior Associate Chair of the Department of Family Practice and a board-certified family physician. He has advanced training in research design and statistics from the University of Michigan School of Public Health.

Additionally, Dr. Barry has completed a faculty development fellowship and assists in learning evaluation. He will conduct the focus groups to evaluate the CRGS, and will assist with the workshop training and data analysis. He will also work closely with the intervention faculty to develop an advanced program to be offered at the annual meeting of the Society of Teachers of Family Medicine for faculty of the family practice residencies who are interested in adopting the intervention.

Before becoming a pointy-headed academic, Dr. Barry practiced in rural Appalachia for four years where he developed a deep appreciation for real world issues.

Barbara Given, Ph.D., R.N., F.A.A.N.

Barbara Given is a professor in the College of Nursing and senior research scientist with the Institute for Managed Care at Michigan State University. She has been actively involved in research in long-term care, home care, chronic illness and family involvement for over 25 years with funding from the National Cancer Institute, National Institute of Mental Health, National Institute for Nursing Research, National Institute on Aging, Walther Cancer Institute, Michigan Department of Community Health, and the American Cancer Society to explore these issues. Topics of research center around functional outcomes, symptom control, patterns of care, utilization of care, and formal/ informal cost of care for the chronically ill and their family caregivers. She is a reviewer for numerous professional journals and currently serves on the editorial board for *Research in Nursing and Health*, and *Cancer Nursing*.

Dr. Given has served as a grant reviewer for AHCPR, Psychosocial Research for the American Cancer Society, NCI NINR, Department of Defense, NIA, California Breast Cancer Research Program, and the Alzheimer's Association of Canada. In addition to testifying to The President's Breast Cancer Commission and The President's Cancer Panel for Older Populations in 1997, Barbara Given served on the Institute of Medicine's Department of Defense Panel to decide on priorities for breast cancer research funding. She also served on the Blue Ribbon Panel for ACS to set direction for research for Behavioral and Psychosocial Research.

In 1994 Barbara Given was recipient of The American Nursing Foundation Distinguished Researcher Award. In 1995 she was the ONS Distinguished Researcher and also received the Michigan Association of Governing Boards Distinguished Faculty Award.

Thomas J. Zuber, M.D.

Dr. Thomas Zuber is the former residency director for the Saginaw Cooperative Hospitals Family Residency Program. As a board-certified family physician with extensive experience teaching practicing physicians and residents, he is widely recognized as one of the leading educators in family medicine procedural skills training. He serves as faculty for many of the American Academy of Family Physicians (AAFP) Continuing Medical Education (CME) courses.

Dr. Zuber created a training program for AAFP on evaluation and management of breast disease and has taught this program extensively throughout the United States.

G. Marie Swanson, Ph.D., M.P.H.

Dr. Swanson is the Director of the Cancer Center at Michigan State University and has extensive experience providing leadership for the conduct of regional and national studies. Her research has concentrated on occupational cancer, strategies for increasing the use of breast cancer screening, and racial differences in breast cancer risk. Dr. Swanson has researched and extensively written on breast cancer and the barriers to screening. Her expertise in this area, her involvement on the President's Breast Cancer panel, and her knowledge of what is important in determining barriers to screening and reaching people are essential.



ESSENTIALS OF BREAST CARE

CURRICULUM OUTLINE

Essentials of Breast Care Curriculum

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Essentials of Breast Care

**Janet R. Osuch, M.D., M.S.
Dorothy R. Pathak, Ph.D., M.S.
Henry C. Barry, M.D., M.S.
Thomas J. Zuber, M.D.**

Funded by Department of Defense #DAMD17-98-1-8318

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 1

Breast Cancer in the U.S.

	<u>Estimated #/Year</u>	
	<u>New Cases</u>	<u>Deaths</u>
Women	180,000	43,000
Men	1,500	250

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

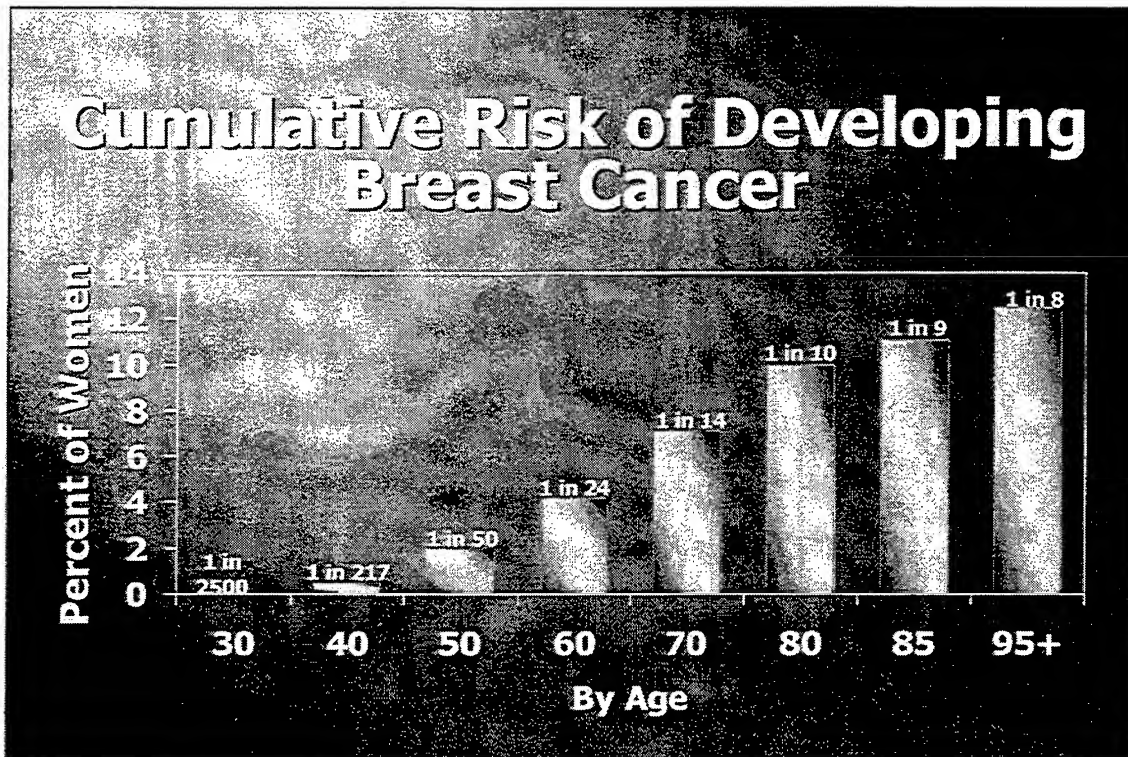
SLIDE 2

Breast cancer is a major public health problem. One of every three cancers diagnosed in American women is breast cancer. It affects an estimated 180,000 women each year and causes over 43,000 deaths. It is the leading cause of death in women aged 35-54.

Breast cancer can also affect men. As a comparison, approximately 1,500 are diagnosed annually, and 250 men die from breast cancer each year.

Sources:

1. American Cancer Society. Cancer Statistics 2000, Atlanta, GA. American Cancer Society, 2000.
2. Vital Statistics of the United States 2000.



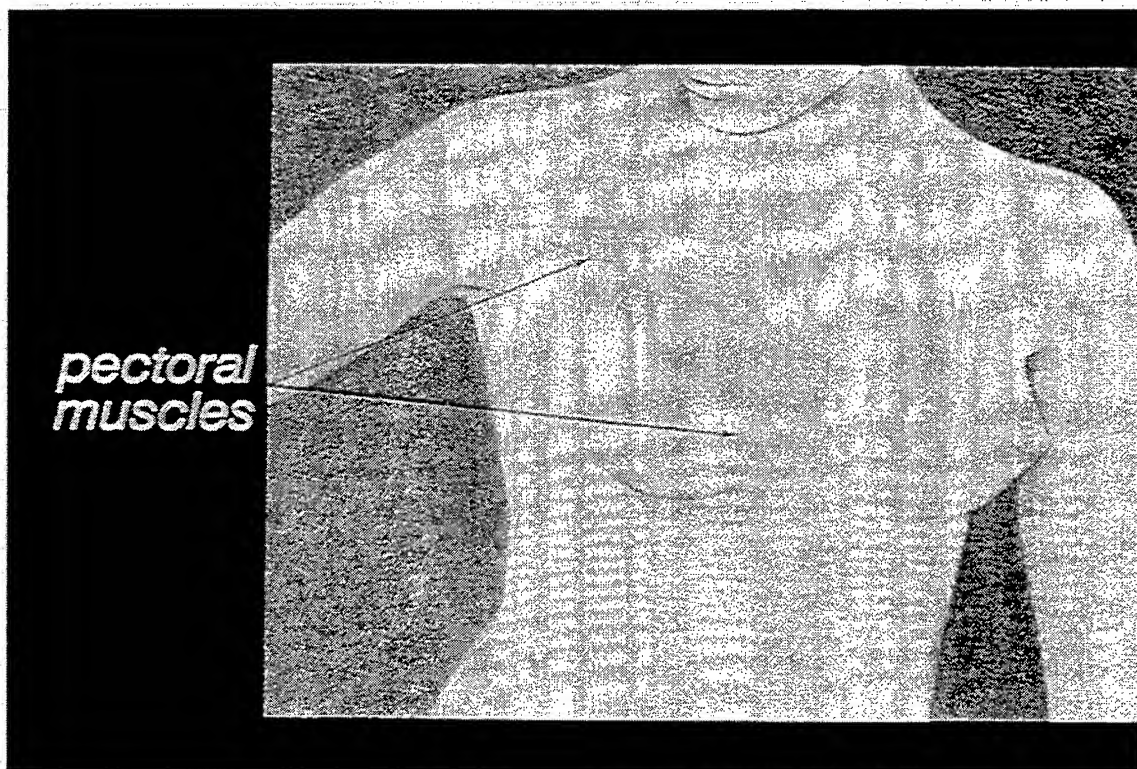
Slide Credit: Modified from a slide courtesy of the American Cancer Society, Atlanta, GA. Public Domain.

SLIDE 3

This slide shows the risk of developing breast cancer by a given age. One in nine (11.8%) women in a cohort followed from birth to age 85 will be diagnosed with Breast carcinoma during her lifetime, and one in eight (12.5%) in a cohort followed From birth to age 95+ years. Women should be told that these risks are calculated Starting at birth rather from her current age. Unlike most cancers, breast cancer can strike even young age groups, although the overall incidence is lower than in older women. It is helpful to interpret risk according to age for patients, who often overestimate their actual risk. Do not disregard the risk in premenopausal women, however. Over 44,000 women less than age 50 are diagnosed with breast cancer in the United States annually. This is greater than the incidence of uterine and ovarian cancer combined across a woman's entire lifespan.

Sources:

1. Feuer EJ, Wun LM, Boring CC, et al. The lifetime risk of developing breast cancer. *J Natl Cancer Institute* 1993; 85:892-897.
2. Osuch JR, Bonham VL. The timely diagnosis of breast cancer. *Cancer* 1994;74:271-278.



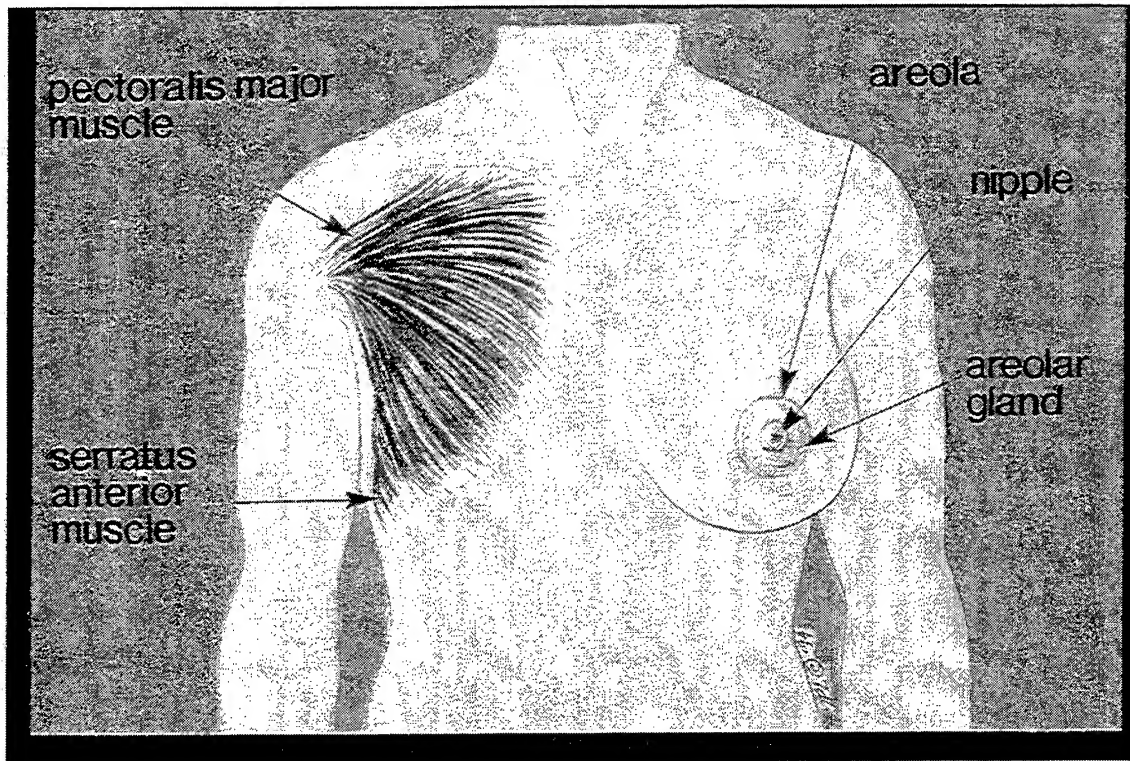
Slide Credit: National Cancer Institute. Bethesda MD. Public Domain

SLIDE 4

To understand breast cancer, it is useful to review the anatomy of the breast. The breast rests on top of the pectoralis major muscle. Many women believe that there are muscles inside of the breast and attribute a new finding on breast self-exam (BSE) to being muscular in nature. The nipple-areolar complex is the only portion of the breast that has a muscular component. It is circular in nature and assists in lactation. This muscle is not palpable.

Source:

Breast anatomy and physiology. In: Hughes LE, Mansel RE, Webster DJT (Eds). *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management*. London: Bailliere Tindall, 1989. pp. 5-13.



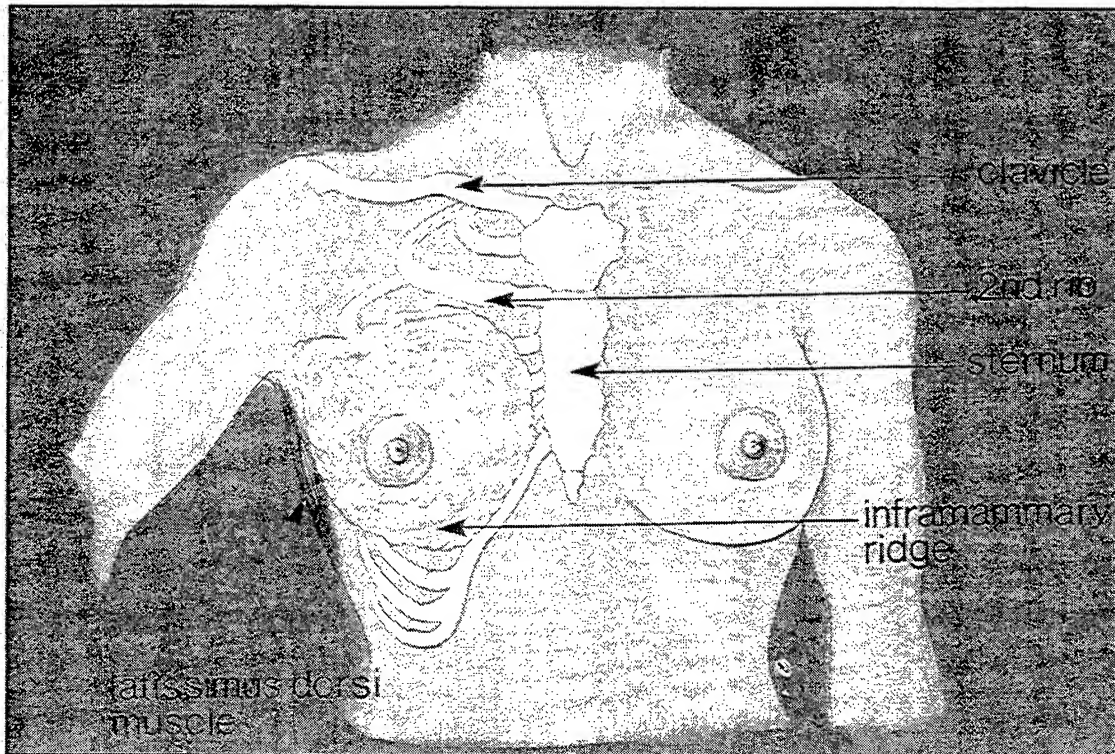
Slide Credit: Slide No. 11 from Osuch JR, Dell DL, Sleighter S. *Breast and Cervical Cancer Education for Primary Care Providers*. Alexandria, VA: American Medical Women's Association. 1994, Joyce Lavery, MFA, CMI. Used with permission.

SLIDE 5

In most women, and especially in large-breasted women, the breast also covers the anterior portion of the serratus anterior muscle. Many women refer to the nipple-areolar complex as the "nipple". The two structures need to be distinguished when a breast complaint is specific to this region.

Source:

Breast anatomy and physiology. In: Hughes LE, Mansel RE, Webster DJT (Eds). *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management*. London: Bailliere Tindall, 1989, pp. 5-13.



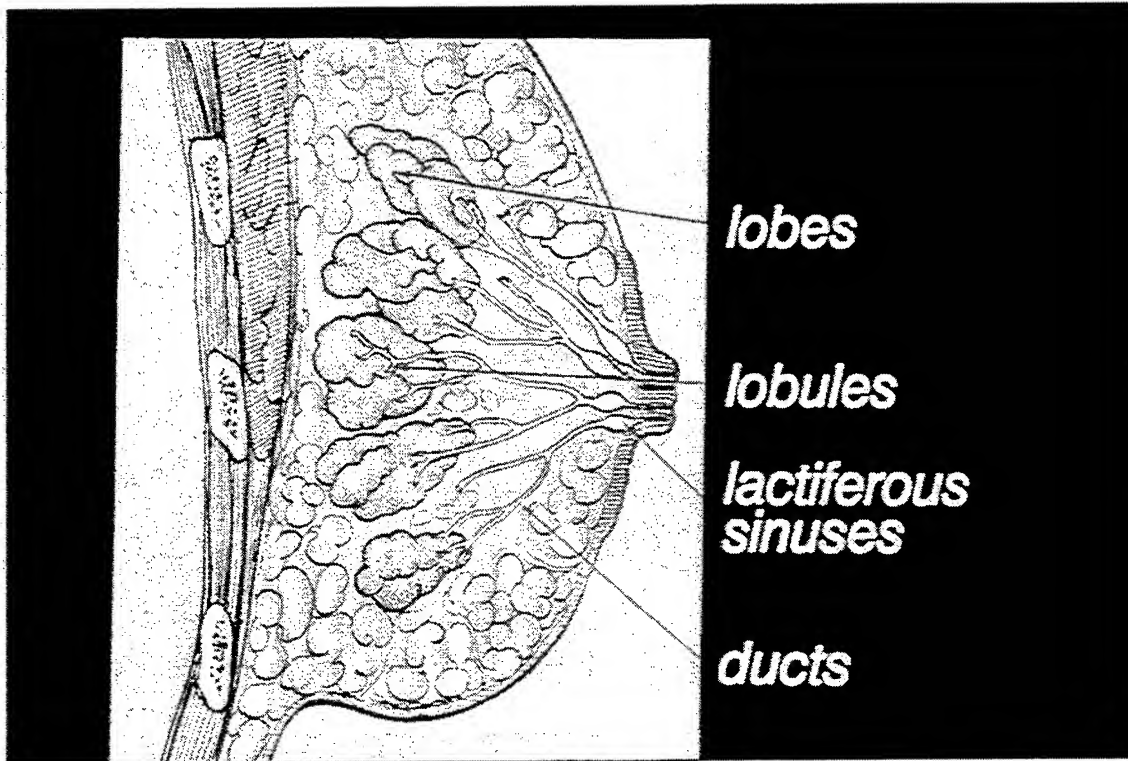
Slide Credit: Slide No. 12 from Osuch JR, Dell DL, Sleighter S. *Breast and Cervical Cancer Education for Primary Care Providers*. Alexandria, VA: American Medical Women's Association. 1994. Joyce Lavery, MFA, CMI. Used with permission.

SLIDE 6

Anatomically, breast tissue is enclosed in fascia, which extends to the second rib near the clavicle, and inferiorly to the inframammary ridge near the fifth rib. This ridge is often quite bumpy, and can sometimes be mistaken for a breast mass. However, a similar, symmetrical ridge will be found in a mirror image location in the opposite breast. Medially, breast tissue extends anatomically to the lateral edge of the sternum and laterally, to the latissimus dorsi muscle.

Source:

Breast anatomy and physiology. In: Hughes LE, Mansel RE, Webster DJT (Eds). *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management*. London: Bailliere Tindall. 1989. pp. 5-13.



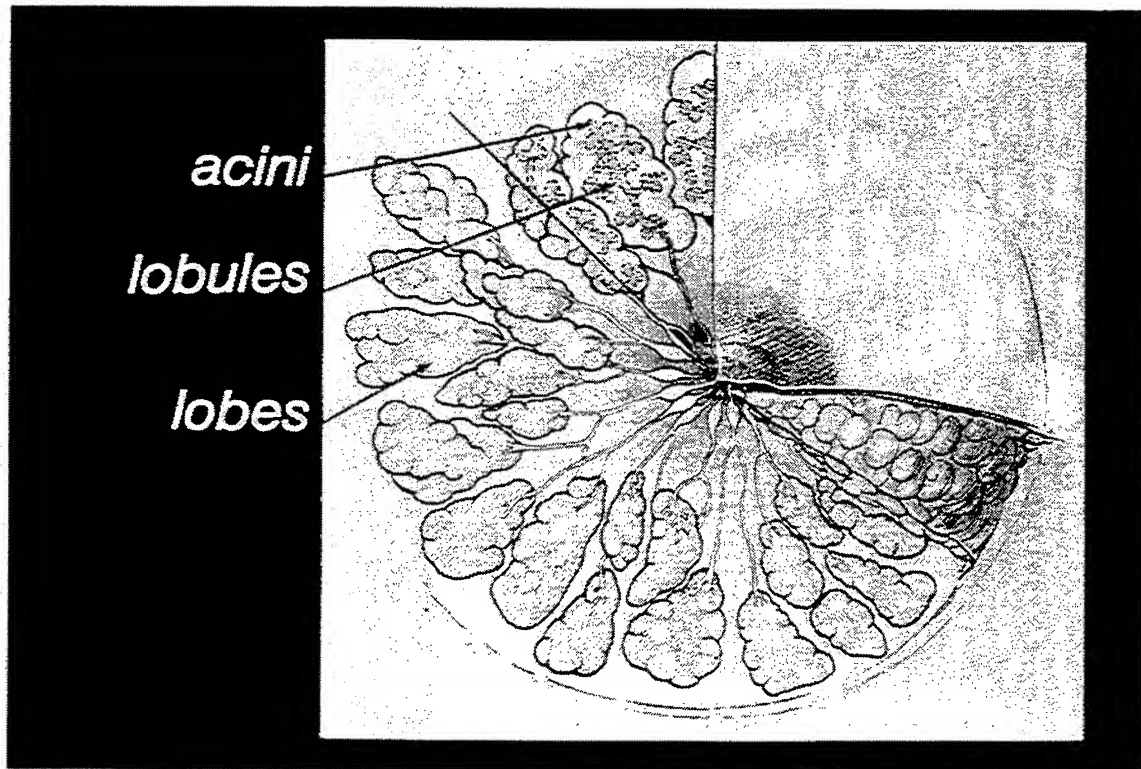
Slide Credit: National Cancer Institute, Bethesda MD. Public Domain

SLIDE 7

The internal anatomy of the breast can be viewed as a system of branching tree-like structures embedded in adipose and connective tissue. The parenchymal tissue is composed of two types: the lobes, which secrete milk; and the ducts, which transport the milk to the nipple. Each lobular element is drained by a small duct, which enlarges as it courses towards the nipple and ends as a lactiferous sinus, whose function is to store milk. These structures are located posterior to the areola and often can be palpated as a bumpiness at that location. Circular muscle contraction of the nipple stimulated by suckling empties the lactiferous sinuses to initiate lactation.

Source:

Breast anatomy and physiology. In: Hughes LE, Mansel RE, Webster DJT (Eds). *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management*. London: Bailliere Tindall. 1989. pp. 5-13.



Slide Credit: National Cancer Institute, Bethesda MD, Public Domain

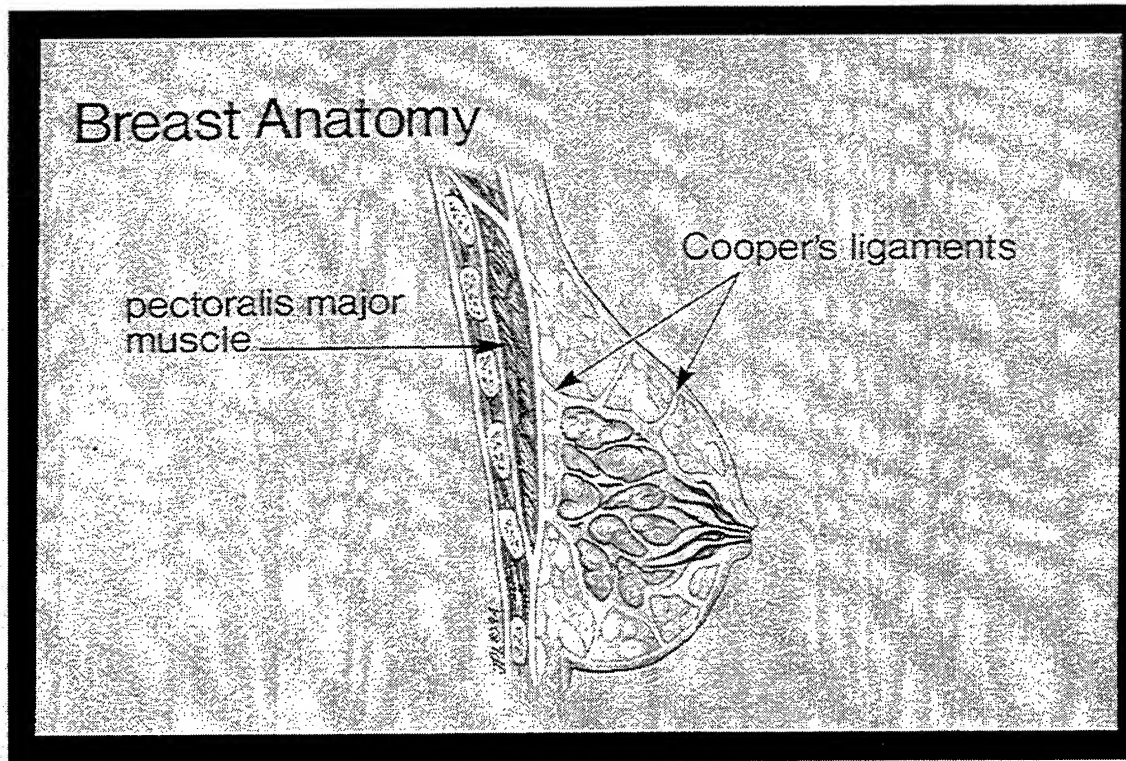
SLIDE 8

This frontal view of the breast demonstrates that the lobules divide into acini, the milk-producing structures. During pregnancy or lactation, the acini enlarge. Each lobe is drained by a major duct system, with 12-20 separate major ducts within the breast.

Note the lactiferous sinuses in this frontal view just beneath the nipple-areolar complex.

Source:

Breast anatomy and physiology. In: Hughes LE, Mansel RE, Webster DJT (Eds). *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management*. London: Bailliere Tindall, 1989, pp. 5-13.



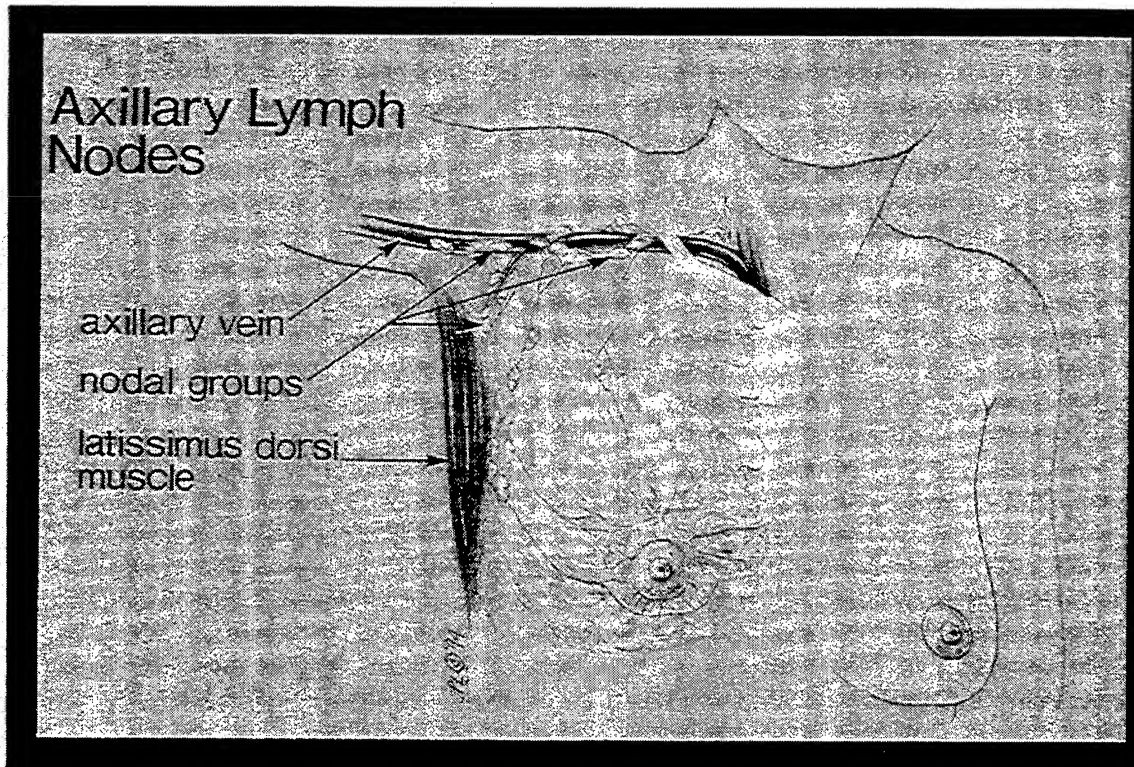
Slide Credit: Slide No. 16 from Osuch JR, Dell DL, Sleighter S. *Breast and Cervical Cancer Education for Primary Care Providers*. Alexandria, VA: American Medical Women's Association. 1994, Joyce Lavery, MFA, CMI. Used with permission.

SLIDE 9

Cooper's ligaments, composed of connective tissue, are attached to the fascia below the skin, as well as to the fascia of the pectoralis major muscle. These ligaments become important in the physical examination of the breast, as we will discuss later.

Source:

Breast anatomy and physiology. In: Hughes LE, Mansel RE, Webster DJT (Eds), *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management*. London: Bailliere Tindall. 1989, pp. 5-13.



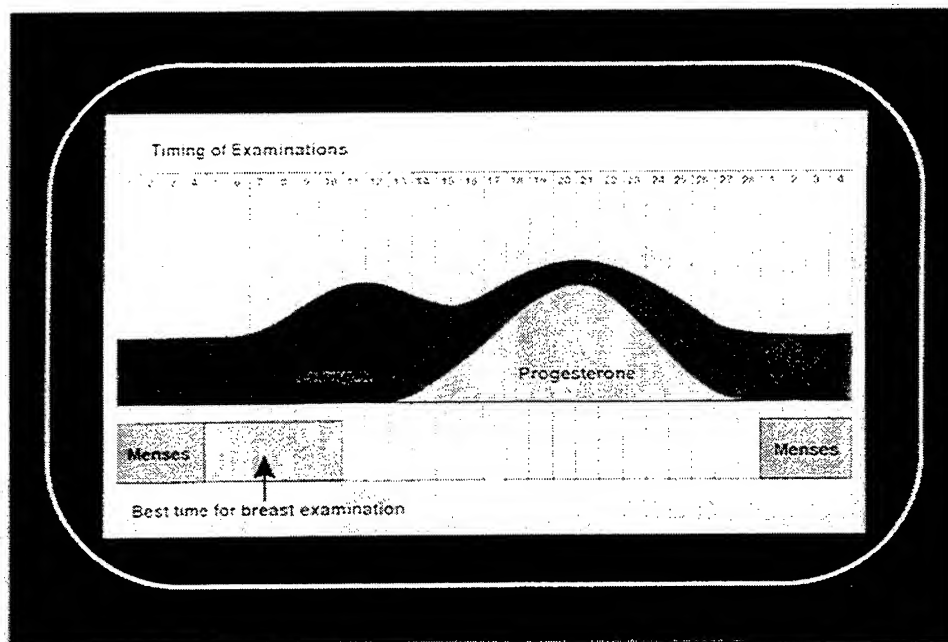
Slide Credit: Slide No. 17 from Osuch JR, Dell DL, Sleighter S. *Breast and Cervical Cancer Education for Primary Care Providers*. Alexandria, VA: American Medical Women's Association. 1994, Joyce Lavery, MFA, CMI. Used with permission.

SLIDE 10

The majority of breast tissue is drained by axillary lymph nodes, which extend from the axilla along the axillary vein and into the infraclavicular and supraclavicular nodal groups. Some are removed when an axillary dissection is performed to stage breast cancer. This slide also illustrates the anatomical limits of the breast. Note the breast tissue extending into the axilla.

Source:

Breast anatomy and physiology. In: Hughes LE, Mansel RE, Webster DJT (Eds), *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management*. London: Bailliere Tindall, 1989, pp. 5-13.



Slide Credit: Slide No. 20 from Osuch JR, Dell DL, Sleighter S. *Breast and Cervical Cancer Education for Primary Care Providers*. Alexandria, VA: American Medical Women's Association, 1994. Joyce Lavery MFA, CMI. Modified after John A Craig, M.D., Illustrator. In: Townsend, CM. *Breast Lumps*. New Jersey: Ciba Pharmaceutical Company. Clinical Symposia 1080. 32:7. Used with permission.

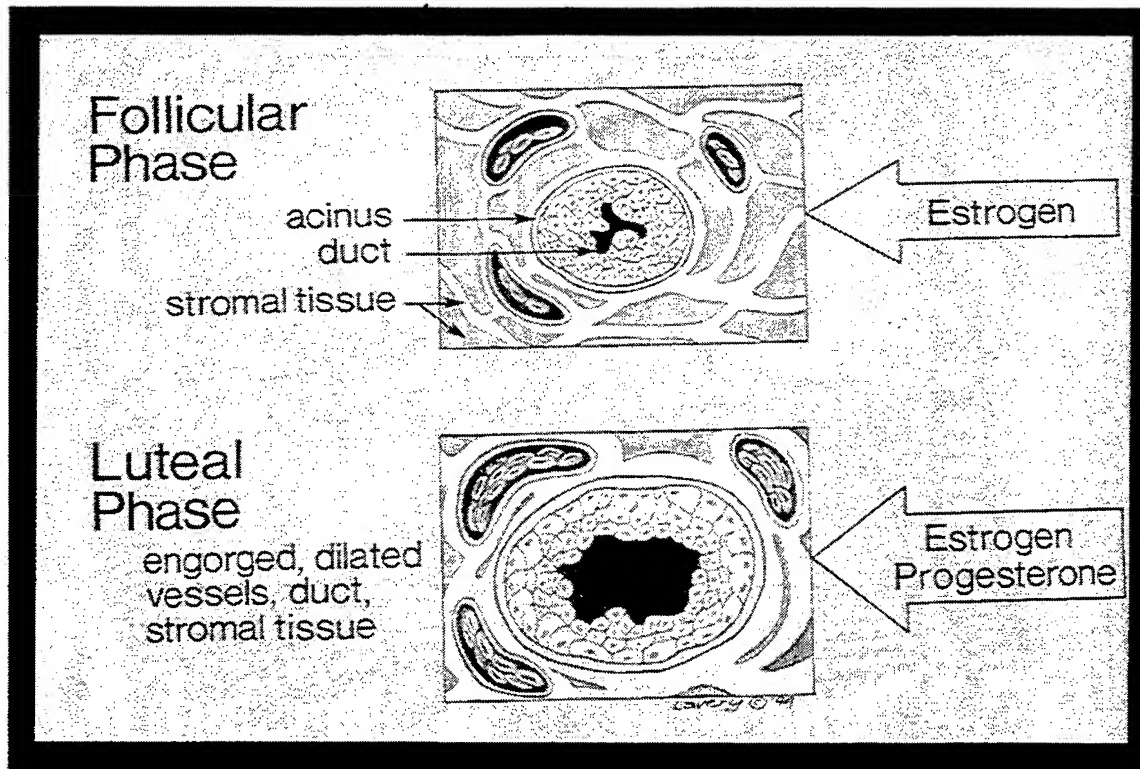
SLIDE 11

The ovarian hormones estrogen and progesterone have a profound physiological effect on breast tissue. This slide illustrates the estrogen and progesterone peaks at the various days of the menstrual cycle. Between days 1 through 7, estrogen levels are at a low point and progesterone is not present. This follicular phase ends at about day 14, when ovulation results in the production of progesterone and the luteal phase begins.

The optimal time for examining the breast is in the follicular phase of the menstrual cycle, preferably between days 3 and 10. The breasts are least tender at this time, least nodular, and the exam easier to interpret than in the luteal phase.

Source:

Breast anatomy and physiology. In: Hughes LE, Mansel RE, Webster DJT (Eds), *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management*. London: Bailliere Tindall, 1989. pp. 5-13.



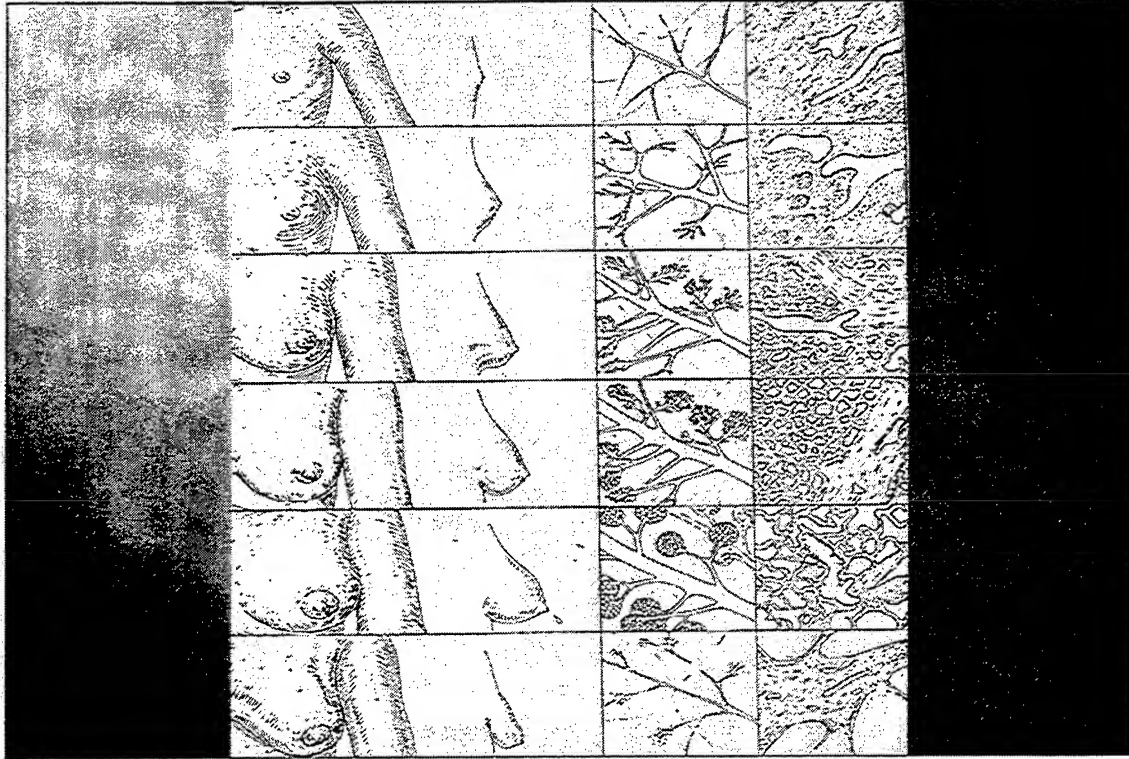
Slide Credit: Slide No. 19 from Osuch JR, Dell DL, Sleighter S. *Breast and Cervical Cancer Education for Primary Care Providers*. Alexandria, VA: American Medical Women's Association, 1994. Joyce Lavery MFA, CMI. Modified after John A Craig, M.D., Illustrator. In: Townsend, CM. *Breast Lumps*. New Jersey: Ciba Pharmaceutical Company, Clinical Symposia 1080, 32:11. Used with permission.

SLIDE 12

The top illustration in this slide demonstrates the appearance of breast tissue in the presence of estrogen alone, whereas the bottom illustration represents the effect of both estrogen and progesterone. Note that in the presence of progesterone, the stromal tissue is engorged and dilated, as is the duct, located in the center of the illustration. The blood vessels also are dilated and engorged with red blood cells. Looking at these illustrations, it is not difficult to understand why many ovulating women have breast pain during the luteal phase of their cycle. The breasts may also be more nodular to palpation during the luteal phase.

Source:

Breast anatomy and physiology. In: Hughes LE, Mansel RE, Webster DJT (Eds), *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management*. London: Bailliere Tindall, 1989, pp. 5-13.



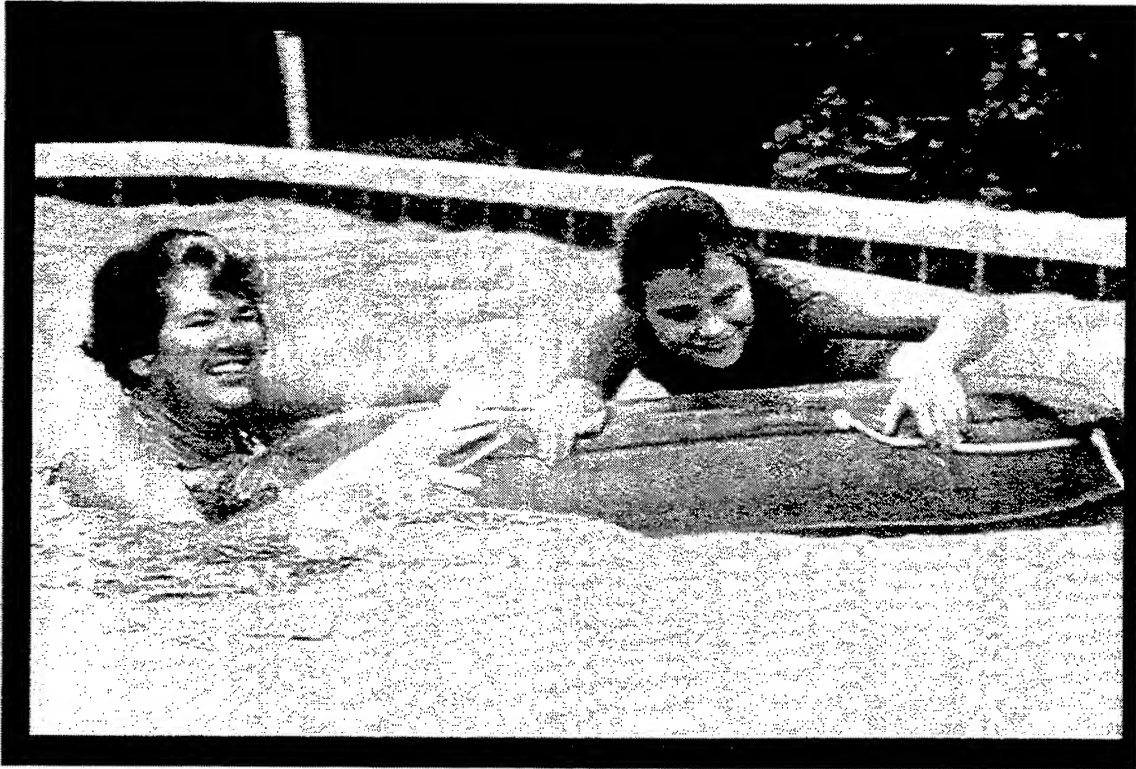
Slide Credit: from Copeland EM, Bland KI. The breast, Chapter 17, figure 7. In: Sabiston DC (ed): *Essentials of Surgery*. Philadelphia, PA: W.B. Sanders, 1987. Used with permission.

SLIDE 13

An understanding of how the breast changes across a woman's lifecycle can increase an examiner's confidence in his or her findings on breast examination. This slide illustrates the phases of breast development, and correlates the frontal and lateral surface anatomy with the internal and microscopic anatomy. The breasts at birth contain all of the structures needed for development at puberty, and remain dormant until then. In pre-pubertal stages, ducts are present but nonfunctional (A). At the onset of puberty, estrogen stimulates elongation and branching of the ducts and growth of connective tissue within the breast (B). Lobular formation is dependant on progesterone and is absent until the onset of ovulation (C). The full maturation of breast epithelium depends on full-term pregnancy, which stimulates marked proliferation of duct and lobular cells (D). In lactating women, the proliferating lobules remain engorged until weaning (E). The number of breast cells recedes after delivery, but remains elevated above that of nulliparous women. In the perimenopausal woman, the lobules begin to recede, leaving mostly ducts and fibro-connective tissue. Perimenopausal women often develop cysts in the breasts as the lobular elements recede. At menopause, the lobules completely atrophy, leaving ducts, adipose, and connective tissue (F).

Source:

Breast anatomy and physiology. In: Hughes LE, Mansel RE, Webster DJT (Eds), *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management*. London: Bailliere Tindall. 1989, pp. 5-13.



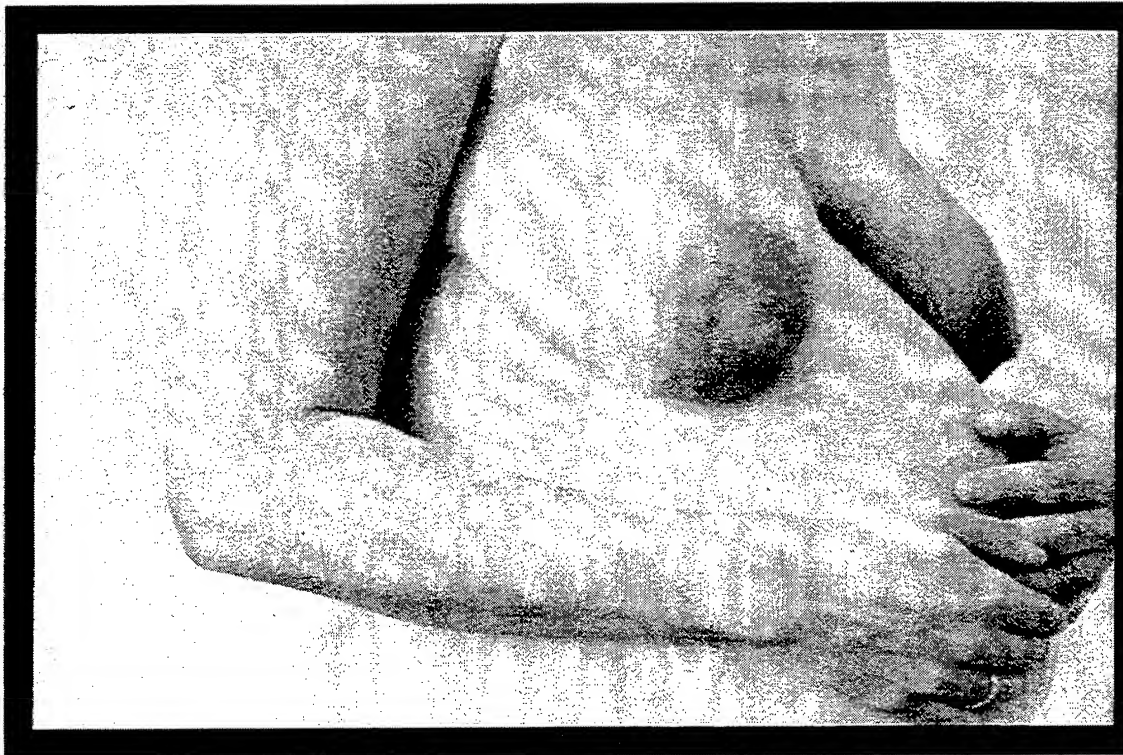
Slide Credit: National Cancer Institute, Bethesda MD, Public Domain

SLIDE 14

At the onset of puberty, breast buds appear as retroareolar masses. It is important to recognize this as normal. Young girls are sometimes inappropriately referred to surgeons because of a retroareolar breast mass. Removal of the breast bud is a tragic event as all breast tissue is essentially removed, and breast development will not occur.

Source:

Bland KI and Rommell LJ: Congenital and acquired disturbances of breast development and growth. In: *The Breast: Comprehensive Management of Benign and Malignant Diseases*. Bland KI and Copeland EM (Eds)., 2nd Edition. Philadelphia, PA: W.B. Saunders. 1998.



Slide Credit: National Cancer Institute, Bethesda MD, Public Domain

SLIDE 15

The first prenatal visit should document results of CBE, as examination early in pregnancy is the time when CBE interpretation is the most sensitive and accurate. As pregnancy proceeds, lobular cells become engorged with colostrum and CBE interpretation can be challenging. During pregnancy, the breast increases to about twice its normal weight. The hypervascularity of the breast during pregnancy sometimes results in bloody nipple discharge. Bloody nipple discharge in the second and third trimesters of pregnancy, as well as at the beginning stages of lactation, is normal and almost always regresses spontaneously.

Source:

Goodson WH, and King EB. Discharges and secretions of the nipple. In: *The Breast: Comprehensive Management of Benign and Malignant Disease*. Bland KI and Copeland EM (Eds). 2nd Edition. Philadelphia, PA: W.B. Saunders. 1998.



Slide Credit: National Cancer Institute, Bethesda MD. Public Domain

SLIDE 16

Lactation is stimulated within 2-5 days of birth by high prolactin levels and the loss of circulating placental hormones. In lactating women, the breast should be emptied 20 minutes prior to CBE for optimal interpretation.



Slide Credit: National Cancer Institute, Bethesda MD, Public Domain

SLIDE 17

CBE in postmenopausal women is by comparison far easier to interpret than in premenopausal women, due to diminished density and nodularity. However, the breasts of a subset of postmenopausal women who take hormone replacement therapy (HRT) will convert back to the premenopausal state. These changes have been documented by CBE, by mammography, and by histopathology. A physiologic explanation for why this occurs, especially in only a subset of women, is lacking. However, clues to the etiology have recently been explained by the increased proliferation of epithelial cells that occurs in women on hormone replacement therapy.

Sources:

1. Powell DE. The normal breast: Structure, function, and epidemiology. In: Powell DE, Stelling CB (eds): *The Diagnosis and Detection of Breast Disease*. St. Louis, MO: Mosby, 1994, pp 3-20.
2. Hofseth LJ, Raafat AM, Osuch JR, Pathak DR, Slomski CA, Haslam SZ. Hormone replacement therapy with estrogen or estrogen plus medroxyprogesterone acetate is associated with increased epithelial proliferation in the normal postmenopausal breast. *J Clin Endocrinol Metab* 1999; 84:4559-4565.

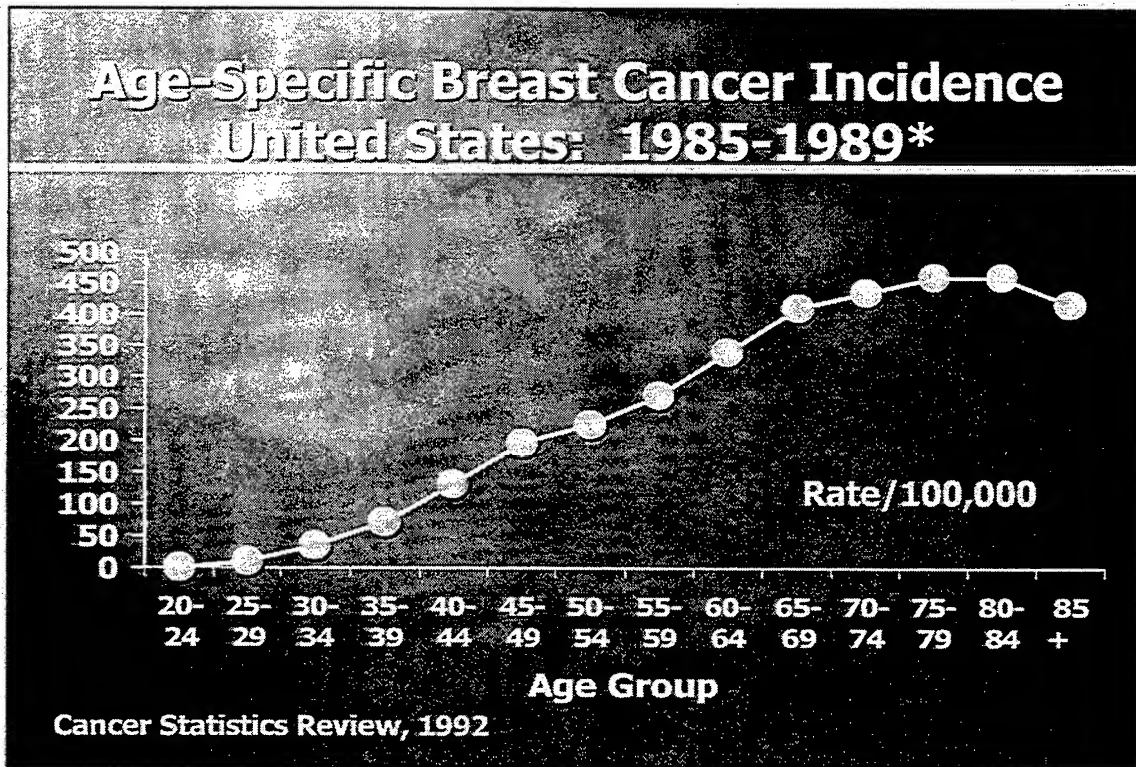


Epidemiology of and Risk Factors for Breast Cancer

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 18

This section is meant to give you practical information regarding risk assessment. To interpret this topic, which often generates fear and confusion, we need to address a few common terms.



Slide Credit: Modified from Love N. *Primary Care Considerations in Breast Diagnosis*. Slide-lecture program. Slide No. 7. Tampa, FL: American Cancer Society, Florida Division. 1992. Used with permission.

SLIDE 19

This slide demonstrates breast cancer incidence expressed as the rate of breast cancer per 100,000 women according to 5-year age groups. It illustrates that starting in age group 20-24, breast cancer incidence rises continuously through age group 80-84, with a slight decrease in the 85+ age group.

Source:

Miller BA et al. *Cancer Statistics Review, 1973 - 1989* U.S. Department of Health and Human Services.

ABSOLUTE RISK

Incidence of breast cancer

**New cases of breast cancer
arising in a population
over a fixed time period**

**Population at risk
during that time period**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University. 2000.

SLIDE 20

When interpreting risk factor information for patients, it is important to understand the difference between absolute and relative risk. This slide demonstrates how absolute risk is calculated. It is an expression of incidence of disease and is time dependent. Some commonly used time intervals include 1-year (annual), 5-year, and lifetime expressions of risk. Assuming a life expectancy of 85 years, the lifetime absolute risk of breast cancer is approximately 11%, or one in nine.

Source:

Last JM. *A Dictionary of Epidemiology*. New York, NY: Oxford University Press. 1995.

ABSOLUTE RISK

**Incidence of breast
cancer in women
WITH risk factor**

**Incidence of breast
cancer in women
WITHOUT risk factor**

**Women *WITH* risk
factor who will develop
breast cancer**

**All women with risk
factor in a population**

**Women *WITHOUT* risk
factor who will
develop breast cancer**

**All women without risk
factor in a population**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 21

Absolute risk calculations can also be applied to specific populations. Two examples of such an application are illustrated on this slide. On the left, the formula for calculating incidence of breast cancer in women with a particular risk factor is shown. On the right, the same calculation is shown for women without the risk factor. Both represent absolute risk calculations. Remember that the calculation is time-dependent.

Source:

Last JM. *A Dictionary of Epidemiology*. New York, NY: Oxford University Press, 1995.

RELATIVE RISK

Incidence of breast
cancer in women
WITH risk factor

Incidence of breast
cancer in women
WITHOUT risk factor

Women *WITH* risk
factor who will develop
breast cancer

All women with risk
factor in a population

•

•

Women *WITHOUT* risk
factor who will
develop breast cancer

All women without risk
factor in a population

Slice Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 22

The term RELATIVE RISK is not a rate, like incidence, but instead is expressed as a ratio. It compares the incidence of disease in a group with a particular risk factor to the incidence of disease in a group without that factor. Remember that relative risk is a comparative likelihood of disease development, as compared with absolute risk, which expresses the underlying probability of disease during a specified time period. This slide illustrates this concept. It compares the same two populations for which the previous slide calculated incidence.

Source:

Last JM. *A Dictionary of Epidemiology*. New York, NY: Oxford University Press, 1995.

Relative Risk Example

<u>Family History</u>	<u>New Cases of Breast Cancer in a Fixed Time Period</u>
Present N = 100	8
Absent N = 400	16

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 23

Let us consider a theoretical example of a cohort of 500 women followed for a set period of time. One hundred women have a family history of breast cancer and 400 do not.

Eight women are diagnosed with breast cancer in the first group and sixteen in the second. What is the absolute risk for the two groups for the time period of the study?

What is the the relative risk in women with a family history of breast cancer versus those without such a history? How are these two types of risk interpreted?

Relative Risk Example

Family History in Theoretical Cohort Study

$$\frac{8/100}{16/400} = \frac{.08}{.04} = 2.0$$

Interpretation

- **Double the risk**
- **Twice the risk**
- **100% increase in risk**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 24

The absolute risk in the group with the family history is 0.08 or 8% during the period of observation. In the group without a family history, the absolute risk is 0.04 or 4% during the same period of observation. The relative risk for breast cancer in a woman with a family history of the disease is 2.0. This could be reported as double the risk, twice the risk, or a 100% increase in risk. All expressions mean the same thing and refer to the proportionate increase in risk in the group of women with a family history compared to the group without a family history over the time period investigated in this study.

Source: Osuch JR, Bonham VL, Morris LL. *Primary Care Guide to Managing A Breast Mass: Step-by-Step Work Up*. Medscape Women's Health, 1998; Vol 3. No. 5. <http://www.medscape.com> (See instructions in Appendix 10.)

Cautions Regarding *Risk Interpretation:*

- Know the difference between absolute and relative risk
- Do not multiply lifetime absolute risk by relative risk for a defined time period
- Do not add relative risk values
- Remember that both relative and absolute risk can change with time

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 25

Several points should be emphasized regarding risk interpretation. Remember that **absolute risk** is a **probability**, usually expressed in **percentage**. Relative risk is a number which represents a comparison, or ratio, between one group and another.

The lifetime absolute risk of the general population cannot be multiplied by the relative risk of an individual woman. As an example, a woman who had a relative risk of 5.0 due to a history of atypical hyperplasia was told that her risk for developing breast cancer was five times the commonly used lifetime risk of 10%, making her risk 50%. She was advised to consider bilateral prophylactic mastectomies based on this information, which she elected to have performed. She successfully sued the physician for unnecessary surgery based on inaccurate informed consent.

It is also not valid to add relative risks. For example, this same woman with a relative risk of 5.0 based on a history of atypical hyperplasia who also had a relative risk of 2.5 due to family history of breast cancer, could have a higher or lower overall relative risk than 7.5.

Whenever interpreting absolute and relative risks, remember that **time** is an important factor. A 40 year old woman with the same risk profile as a 70 year old will have a higher lifetime risk of breast cancer simply because she will have a greater number of years to live.

Source:

Last JM. *A Dictionary of Epidemiology*. New York, NY: Oxford University Press, 1995.

Practical Breast Cancer Risk Counseling in the Individual Patient

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

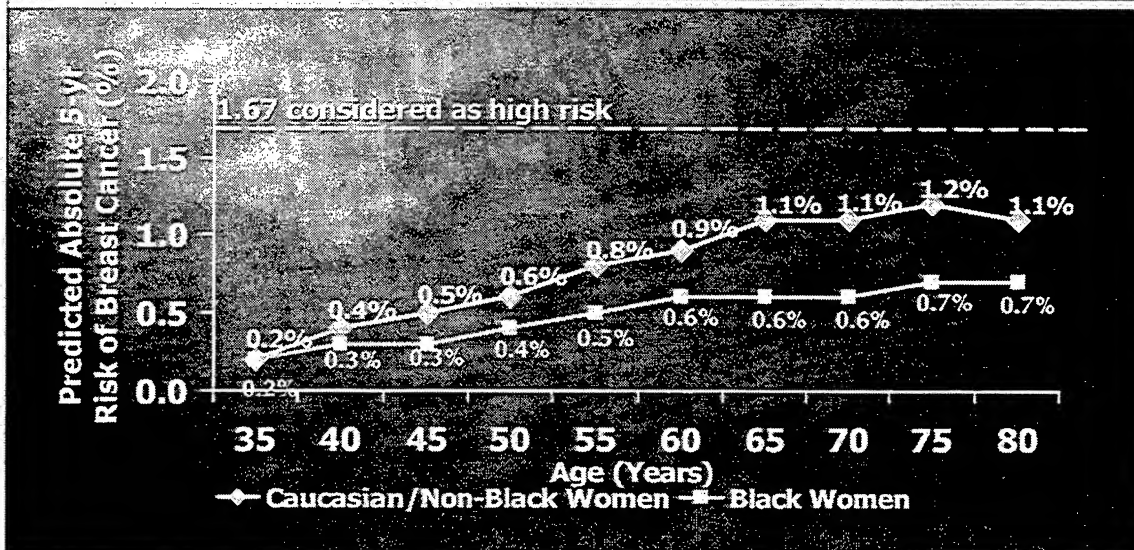
SLIDE 26

A useful device in the interpretation of risk factors for the individual patient is the Gail Model Risk Assessment Tool, developed and validated by the National Cancer Institute and used to assess risk in the clinical trials evaluating breast cancer prevention. The data used in predicting individual risk were based on results derived from follow-up of over 280,000 women who participated in the Breast Cancer Detection Demonstration Project (BCDDP). Estimates of relative risks were based on analysis of approximately 3,000 observed cases and an equal number of controls from this study. The calculated risk projections using this model are most reliable for counseling women who have annual examinations.

Source:

Gail MH, Brinton LA, Byar DP, et al. Projecting individualized probabilities of developing breast cancer for white females who are being examined annually. *J Natl Cancer Inst* 1989;81:1879-1886.

Predicted Absolute 5-Year Breast Cancer Risk for Caucasian/Non-Black and Black Women Based on Age Alone and No Other Known Risk Factors



Slide Credit: Modified from the *Breast Cancer Risk Assessment and Counseling Kit*. Wilmington, DE: AstraZeneca Pharmaceuticals, 1999. Used with permission.

SLIDE 27

This slide demonstrates the predicted absolute 5-year risk of breast cancer by age for theoretical groups of Caucasian/Non-Black and Black women considered to be at the lowest risk for the disease. The defined criteria for lowest risk include three factors: (1) age at menarche of 14 years or greater, (2) age at first full-term pregnancy of 18 years or less, and (3) no additional risk factors for breast cancer. For women 40 years and older, the risk ranges between 0.3% and 1.2% for the subsequent 5-year period. The risk tends to be lower in Black women, between 0.3% and 0.7%.

Source:

Gail MH, Brinton LA, Byar DP, et al. Projecting individualized probabilities of developing breast cancer for white females who are being examined annually. *J Natl Cancer Inst* 1989;81:1879-1886.

Practical Risk Counseling for Breast Cancer

The single most
important risk factor for
breast cancer
is the
FEMALE GENDER

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 28

Many women believe that because they do not have certain risk factors for breast cancer, that they are not at risk. It is important to educate women so that they know that all women are at risk and that the most important risk is their gender.

Source:

Osuch JR, Dell D. and Sightler S. *Breast and Cervical Cancer Education for Primary Care Providers*. Alexandria, VA: American Medical Women's Association, 1994.



Slide Credit: National Cancer Institute, Bethesda MD, Public Domain

SLIDE 29

In fact, 75% of women diagnosed with breast cancer have no known risk factors other than gender and age, and 85% have no family history of the disease. The woman at greatest risk for developing breast cancer is elderly, in her seventies and eighties. Unfortunately, this population of women is the least likely to be screened for breast cancer.

Sources:

1. Seidman H, Stellman SD, Mushinski MH. A different perspective on breast cancer risk factors: Some implications of the nonattributable risk. *CA Cancer J Clin* 1982;32(5):301-313.
2. Thompson WD. Genetic epidemiology of breast cancer. *Cancer* 1994;74:279-287.
3. Blustein J. Medicare coverage, supplemental insurance, and the use of mammography by older women. *NEJM* 1995;332:1138-1143.

Risk Factors Used in the **GAIL MODEL**

- **Current age**
- **Age at menarche**
- **Age of first live birth**
- **Family history: First-degree relatives**
- **History of breast biopsy**
- **History of atypical hyperplasia**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 30

Because of the high prevalence of breast cancer, a great deal of research has been performed to understand its etiology. The research generates an abundance of risk factor information, some of which can be misinterpreted. The most practical application for analyzing individual risk is the Gail Model, which includes the risk factors of current age, age at menarche, age at first live birth, family history in first-degree relatives (mother, sister, daughter), and history of breast biopsies, especially if showing atypical hyperplasia.

Source:

Gail MH, Brinton LA, Byar DP, et al. Projecting individualized probabilities of developing breast cancer for white females who are being examined annually. *J Natl Cancer Inst* 1989;81:1879-1886.

Practical Risk Counseling for Breast Cancer

Definition of "**High Risk**"

**5-year absolute risk
of breast cancer of
1.67% or above
based on the
Gail Model.**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 31

The definition of "high risk" is relative. Using the Gail model a 5-year absolute risk of **1.67% or higher** is considered high risk. We will now consider each risk factor individually.

Sources:

1. Fisher B, Constantino JP, Wickerham DL, et al. Tamoxifen for prevention of breast cancer: Report of the National Surgical Adjuvant Breast and Bowel Project P-1 Study. *J Natl Cancer Inst* 1998;90:1371-1388.
2. Nolvadex Patient Counseling Card. AstraZeneca Pharmaceuticals. 1999. Wilmington, DE.

Reproductive Risk Factors Assessed by Gail Model:

<u>Age at Menarche</u>	<u>RR</u>
Age 11 or less	1.2
Age 12 - 13	1.1
Age 14 or more	1.0

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 32

There is correlation between the length of exposure to endogenous ovarian hormones and the risk of breast cancer. Compared with girls whose onset of menarche is 14 or more, the relative risk of those whose menarche began at age 12-13 is 1.1, and those at age 11 or less, 1.2. These are also the age ranges used for onset of menarche in the Gail model calculations.

Source:

Gail MH, Brinton LA, Byar DP, et al. Projecting individualized probabilities of developing breast cancer for white females who are being examined annually. *J Natl Cancer Inst* 1989;81:1879-1886.

Reproductive Risk Factors Assessed by Gail Model:

AGE AT FIRST BIRTH

<u>Age</u>	<u>RR</u> <u>MacMahon</u>	<u>RR</u> <u>Gail</u>
<20	1.0	1.0
20 - 24	1.2	1.2
25 - 29	1.6	1.6
30 - 35	1.9	1.9
35+	2.4	1.9
Nullip	2.0	1.6

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 33

Risk is also influenced by the age at which a woman delivers her first child. Shown here are data from the classic international collaborative case-controlled study by MacMahon, et al., and data from the BCDDP as well. Using women who deliver their first baby at age 20 years or younger as the reference, (comparison group), nulliparous women have a relative risk of between 1.6 and 2.0, depending on the study. Women who deliver their first full-term baby after age 35 had a relative risk of 2.4 in the MacMahon study, but are assessed to be at the same risk as 30-35 year olds in the Gail model. Patients may inquire about the effect of miscarriages, abortions, and multiple births on risk. Miscarried or aborted pregnancies are not protective, nor do they appear to increase risk, although this is a matter of controversy. Multiparity may be protective; however, this has not been consistently observed.

Sources:

1. MacMahon B, Cole P, Lin TM, et al. Age at first birth and breast cancer risk. *Bulletin of the World Health Organization*. 1970;43:209-212.
2. Gail MH, Brinton LA, Byar DP, et al. Projecting individualized probabilities of developing breast cancer for white females who are being examined annually. *J Natl Cancer Inst* 1989;81:1879-1886.

Risk Factors Assessed by Gail Model: *Family History*

<u>Family Member Affected</u>	<u>Pooled RR</u>	<u>Range</u>
NONE	1.0	
One First-Degree Relative (Mother, Sister, Daughter)	2.1	(1.2 - 8.8)
Two First-Degree Relatives	3.6	(2.5 - 13.6)
Second-Degree Relative (Grandmother, Aunt, Niece)	1.5	(1.2 - 1.9)

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 34

A recent meta-analysis of 74 published studies provided pooled estimates of relative risks and the range of the reported risks associated with various family histories. The Gail Model assesses risk only due to family history in first-degree relatives, and includes the number of first-degree relatives affected. First-degree relatives refer to mothers, sisters, or daughters. One affected first-degree relative more than doubles the overall risk, whereas a history in two first-degree relatives could raise the risk to as high as 13.6, which approaches 50% in terms of absolute lifetime risk. Although other family history confers some increased risk, this is not considered in the Gail Model.

Sources:

1. Pahroah PDP, Day NE, Duffy S, et al. Family history and the risk of breast cancer: A systematic review and meta-analysis. *Int J Cancer* 1997;71:800-809.
2. Gail MH, Brinton LA, Byar DP, et al. Projecting individualized probabilities of developing breast cancer for white females who are being examined annually. *J Natl Cancer Inst* 1989;81:1879-1886.

Family History **& Breast Cancer Risk**

<u>FIRST DEGREE RELATIVE</u>	<u>RR</u>
NO HISTORY	1.0
Unilateral/Postmenopausal	1.2
Unilateral/Premenopausal	1.8
Bilateral/Postmenopausal	4.0
Bilateral/Premenopausal	8.8

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University. 1999.

SLIDE 35

The increased risk produced from an affected first-degree relative is influenced by the relative's menstrual status and whether both breasts are involved at the time of diagnosis. The effect of these two factors is not included in the Gail Model, but can signal a genetic predisposition to breast cancer.

You will often see patients who report that their mothers had breast cancer. If only one breast was involved, and the mother was postmenopausal at the time of diagnosis, her daughter's relative risk is very close to that of the woman with no such family history -- 1.2 compared to 1.0. This is reassuring information for your patient. On the other hand, if the first-degree relative was premenopausal at the time of diagnosis and the disease was bilateral, the woman is at significantly higher risk, with a relative risk of 8.8.

Sources:

1. Anderson DE, Badzioch MD. Risk of familial breast cancer. *Cancer* 1985;56:383-387.
2. Lynch HT, Albano WA, Danes BS et al. Genetic predisposition to breast cancer. *Cancer* 1984; 53:612-622.

Risk Factors Assessed by Gail Model: *Breast Biopsies*

<u>Pathologic Result</u>	<u>Frequency</u>	<u>RR</u>
Atypical hyperplasia	4%	5.0
Hyperplasia, no atypia	15%	2.0
Non-proliferative breast changes	80%	1.0

Dupont WD, et al. *NEJM*, 1985

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University. 1999.

SLIDE 36

The Gail Model assesses an increased risk associated with the number of benign breast biopsies performed. The more times a woman needs a biopsy of the breast, the higher the risk, and the more likely proliferative breast changes will be diagnosed. Proliferative changes also predict for increased risk, especially if atypical hyperplasia is diagnosed.

Sources:

1. Dupont WD, Page DL. Risk factors for breast cancer in women with proliferative breast disease. *N Engl J Med* 1985, 146-151.
2. Gail MH, Brinton LA, Byar DP, et al. Projecting individualized probabilities of developing breast cancer for white females who are being examined annually. *J Natl Cancer Inst* 1989;81:1879-1886.

Not Assessed by Gail Model: Personal History of In-Situ or Invasive Breast Cancer

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University. 1999.

SLIDE 37

Patients with breast cancer in their medical history are at a increased risk of developing contralateral breast cancer. The 5-year absolute risk is between 2% and 5% for patients with this history and is not evaluated in the Gail Model.

This statistic actually can be reassuring to most patients with breast cancer, because they generally believe that their risk for developing cancer in the other breast is much higher.

Source:

Hislop TG, Elwood JM, Coldman AJ, et al. Second primary cancers of the breast: Incidence and risk factors. *Br J Cancer* 1985;49:79-85.

Other Factors **Studied in Relation to Breast Cancer:**

- **Lactation History**
- **History of Abortion or Miscarriage**
- **Oral Contraceptive Use**
- **Hormone Replacement Use**
- **Alcohol Use**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 38

There are multiple other associations between exposures and breast cancer risk.

None of these are considered in the Gail Model. However, listed here are the ones that prompt the most common questions from our patients. Let's look at these individually.

Lactation **& Breast Cancer Risk**

- May have a small protective effect for premenopausal breast cancer
- Study results vary
- Largest studies
 - WHO Multicenter Study - no effect
 - Nurses Health Study - no effect

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University. 1999.

SLIDE 39

A history of lactation has been suggested to be a protective factor for a mother's risk of premenopausal breast cancer in some studies, but the largest studies investigating this association found no effect. Women should be advised to breastfeed because of the nutritional benefits to the infant rather than to impact breast cancer risk.

Sources:

1. Thomas DB, Noonan EA. Breast cancer and prolonged lactation. The WHO Collaborative Study of Neoplasia and Steroid Contraceptives. *Int J Epidemiol* 1993; 22:619-626.
2. Michels KB, Willett WC, Rosner BA, et al. Prospective assessment of breast feeding and breast cancer incidence among 89,887 women. *Lancet* 1996; 347:431-437.

Elective Abortion & Breast Cancer Risk

Population-based Danish cohort study 1934-1978

- **1.5 million women**
- **370,715 elective abortions**
- **10,246 women with breast cancer**

CONCLUSION

**No increased risk of breast cancer in either
early or late abortions**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University. 1999.

SLIDE 40

The possible connection between induced abortions and an increased risk of breast cancer has received a great deal of media attention. Some patients may wonder if abortion and breast cancer are linked. Others may question a link between miscarriage and breast cancer risk. There has been no proven link between miscarriage and breast cancer risk. The confusion about both arises from earlier conflicting studies that examined this issue. The largest scientific study of abortion analyzed a cohort of 1.5 million women, over 370,000 who had a history of induced abortions and 10,000 who subsequently developed a history of breast cancer. No association between elective abortion and breast cancer risk was found.

Sources:

1. Melbye M, Wohlfahrt J, Olsen JH, et al. Induced abortion and risk of breast cancer. *JAMA* 1997; 336:81-85.
2. Wingo PA, Newsome K, Marks JS, Calle EE, Parker SL. The risk of breast cancer following spontaneous or induced abortion. *Cancer Causes Control* 1997; 8:93-108.

Oral Contraceptives(OCP) & Breast Cancer Risk

Meta-Analysis 1996

- **54 studies**
- **53,297 women with breast cancer**
- **100,239 women without breast cancer**

Conclusions:

- 1. Increased risk in current users - RR 1.24**
- 2. Increased risk returns to baseline after 5 years have elapsed from last use**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 41

A recent meta-analysis of OCP use and breast cancer risk pooled the data from over 150,000 women in over 50 studies. A 24% increased risk was observed in current users of OCPs, which returned to baseline 5 years after discontinuing use. Women concerned about breast cancer risk and contraceptive choice should be made aware of the slightly increased risk of breast cancer among current and past users within 5 years. Those most concerned are likely to have a family history; this study found no additive effect when women were stratified by family history.

Source:

Breast cancer and hormonal contraceptives: Collaborative reanalysis of individual data on 53,297 women with breast cancer and 100,239 women without breast cancer from 54 epidemiological studies. Collaborative Group on Hormonal Factors in Breast Cancer. *Lancet* 1996; 347:1713-1727.

Hormone Replacement Therapy(HRT) & Breast Cancer Risk

Meta-Analysis 1997

- 51 studies
- 52,705 women with breast cancer
- 108,411 women without breast cancer

Conclusions:

1. Increased risk in current users for ≥ 5 years –
RR 1.35
2. Increased risk returns to baseline after 5 years
have elapsed from last use

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ, Michigan State University, 1999.

SLIDE 42

A recent meta-analysis of HRT use and breast cancer risk examined over 50 studies in over 160,000 women. A 35% increased risk was observed in current users of HRT, which returns to baseline 5 years after discontinuing use. Most of the studies in this meta-analysis examined use of estrogen alone rather than combined therapy with progestins. Evidence currently shows, however, that medroxyprogesterone acetate in combination with estrogen exhibits proliferative effects on breast tissue. In addition, two large studies published in 2000 showed increased breast cancer risks in women who used estrogen-progestin HRT above that of estrogen alone.

Sources:

1. Breast cancer and hormonal replacement therapy. Combined reanalysis of data from 51 epidemiologic studies involving 52,705 women with breast cancer and 108,411 women without breast cancer. Collaborative Group on Hormonal Factors in Breast Cancer. *Lancet* 1997; 350:1047-1059.
2. Hofseth LJ, Raafat AM, Osuch JR, Pathak DR, Slomski CA, Haslam SZ. Hormone replacement therapy with estrogen or estrogen plus medroxyprogesterone acetate is associated with increased epithelial proliferation in the normal postmenopausal breast. *J Clin Endocrinol Metab* 1999; 84:4559-4565.
3. Schairer C, Lubin J, Troisi R, Sturgeon S, Brinton L, Hoover R. Menopausal estrogen and estrogen-progestin replacement therapy and breast cancer risk. *JAMA* 2000; 283:485-91.
4. Ross RK, Paganini-Hill A, Wan PC, Pike MC. Effect of hormone replacement therapy on breast cancer risk: estrogen versus estrogen plus progestin. *J Natl Cancer Inst* 2000; 92:328-332.

Counseling Women on HRT

		No HRT	HRT	
	Annual Mortality		Disease RR	Mortality RR
Breast Cancer	43,000	Ref*	↑	↓
Heart Disease	233,000	Ref*	↓	↓
Osteoporotic hip fracture	65,000	Ref*	↓	↓
*Reference Group				

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 43

When counseling women about HRT use, one should discuss the disease occurrence and mortality risk data for breast cancer, heart disease and osteoporosis. While the risk of developing breast cancer in women using HRT is increased (RR 1.35), the mortality risk from all three diseases is decreased. Cardiovascular disease is much more prevalent than breast cancer and reducing the incidence and mortality for a more prevalent disease provides greater population benefit than influencing a less common condition, and is therefore viewed as beneficial from a public health perspective. The range for the reduction in overall mortality has been reported to be between 21% and 37%. However, the greatest gain in life expectancy (of up to 41 months) is for women with greatest risk for cardiovascular disease and lowest risk for breast cancer. The only women not expected to live longer following the administration of HRT are those at low risk for cardiovascular disease and high risk for breast cancer.

Sources:

1. Col NF, Eckman MH, Karas RH, et al. Patient-specific decisions about hormone replacement therapy in postmenopausal women. *JAMA* 1997;277:1140-1147.
2. Grodstein F, Stampfer MJ, Colditz JA, et al. Post-menopausal hormone therapy and mortality. *N Engl J Med* 1997;336:1769-1775.
3. Cauley JA, Seeley DG, Browner WS et al. Estrogen replacement therapy and mortality among older women. A study of osteoporotic fractures. *Arch Intern Med* 1997;157:2181-2187
4. Schairer C, Adami HO, Hoover R, et al. Cause-specific mortality in women receiving hormone-replacement therapy. *J Natl Cancer Inst* 1999;91:264-270.

Alcohol Intake & Breast Cancer Risk

- **Over 50 studies**
- **Most show an increased risk of 30-40% for ETOH consumption of 1-2 drinks/day**
- **Alcohol may increase the level of circulating estrogen in the bloodstream**
- **Benefit of alcohol on mortality from cardiovascular disease must be considered**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 44

Over 50 studies examining the relationship between breast cancer risk and alcohol intake have been done. Most have shown a 30-40% increase in risk when women ingest 1-2 drinks per day. Alcohol has been reported to alter metabolism and increase the level of circulating estrogen. When counseling women about alcohol intake and breast cancer risk, the beneficial effect of alcohol on cardiovascular risks must be weighed.

Source:

Smith-Warner SA, Spiegelman D, Yaun S-S, et al. Alcohol and breast cancer in women: A pooled analysis of cohort studies. *JAMA* 1998;279:535-540.

***Risk Factors* in Women who Develop Breast Cancer:**

- **75% - none except gender and age**
- **85% - no family history**
- ***ALL* women are at risk!**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 45

It should be re-emphasized that 75% of women diagnosed with breast cancer have no risk factors other than age and gender, and that 85% of women diagnosed have no family history of the disease. In summary, then, all women are at risk for breast cancer, all women should be screened, and all primary care physicians should be confident of their ability to conduct in-office risk counseling. Next we will practice risk counseling using the Gail Model Risk Assessment Tool.

Sources:

1. Seidman H, Stellman SD, Mushinski MH. A different perspective on breast cancer risk factors: Some implications of the nonattributable risk. *CA Cancer J Clin* 1982;32(5):301-313.
2. Thompson WD. Genetic epidemiology of breast cancer. *Cancer* 1994;74:279-287.

Family History & Genetic Predisposition to Breast Cancer

<u>Family History</u>	<u>Distribution of Breast Cancer</u>	<u>Absolute Lifetime Risk</u>
None	80%-85%	11%-12%
One-two postmenopausal relatives	10%	15%-20%
Known genetic mutation	5%-10%	60%-90%

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 46

The Gail Model Risk Assessment Tool does not consider those women who may have inherited a genetic mutation predisposing them to breast cancer. Inherited mutations account for only about 5% to 10% of total breast cancer cases, but it is important to understand the issues pertinent to this topic. If a woman has inherited a genetic mutation predisposing her to breast cancer, her estimated lifetime risk is between 60% and 90%. Compare this with a woman with one or two postmenopausal relatives affected with breast cancer, whose lifetime risk is 15% to 20%. Patients who may have inherited a mutation that might predispose them to breast cancer should receive appropriate education, risk assessment, and counseling.

Source:

Garber JE, Smith BL. Management of the high risk and the concerned patient. In: Harris JR, Lippman ME, Morrow M, and Hellman S (eds). *Diseases of the Breast*. New York, NY: Lippincott - Raven. 1996, pp. 335-341.

Abnormal Genes

Associated with Breast Cancer:

- **BRCA-1 - Chromosome 17**
- **BRCA-2 - Chromosome 13**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 47

All women and men have BRCA-1 and BRCA-2 genes. A mutation of one of these genes is associated with an increased risk of breast cancer. These mutations are inherited in an autosomal dominant pattern and therefore can be passed through the maternal or paternal lineage.

If a parent is affected, there is a 50% probability that the mutation will be passed to the offspring. Men who inherit the mutation may be at a higher risk for cancer, but not breast cancer. However, if a man passes the mutation to a daughter, she will have a lifetime risk for breast cancer of between 60% and 90%, just as if she had inherited the mutation from her mother. In addition, both BRCA1 and BRCA2 mutations are associated with an absolute lifetime risk for ovarian cancer of between 15% and 60% and an increased risk of colon cancer to a level of about 6%.

Source:

Garber JE, Smith BL. Management of the high risk and the concerned patient. In: Harris JR, Lippman ME, Morrow M, and Hellman S (eds). *Diseases of the Breast*. New York, NY: Lippincott - Raven, 1996, pp. 335-341.

BRCA-1 and Cumulative Risk of Breast Cancer

<u>Risk</u>	<u>Group</u>
03.2%	by age 30
19.1%	by age 40
50.8%	by age 50
54.2%	by age 60
85.0%	by age 70

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 48

Similar to the increase in breast cancer risk with age in women without genetic mutations, we see among women with the BRCA-1 mutation an increased risk with age, but it is exaggerated. This slide demonstrates the risk of breast cancer in women with the BRCA-1 mutation by a given age.

Women with breast cancer and no mutation have a 1% per year risk of developing breast cancer in the contralateral breast. Compare this to the woman with the mutation, who has a 64% risk of developing contralateral breast cancer by age 70.

Source:

Burke W, Daly M, Garber J, et al. Recommendations for follow-up care of individuals with an inherited predisposition to cancer. II BRCA1 and BRCA2. Cancer Genetics Consortium. *JAMA* 1997;277:997-1003.

Candidates for BRCA1 & BRCA2 Genetic Susceptibility Testing

- **Women diagnosed with breast cancer prior to age 45**
- **Women diagnosed with ovarian cancer**
- **Women with a family pedigree suggesting breast and/or ovarian cancer**
- **Blood relatives of those who carry a BRCA1 or BRCA2 mutation (*applicable to men or women*)**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 49

Blood tests are available that can identify genetic mutations in BRCA 1 or 2. Many women request these tests without full knowledge of their implications. Potential candidates for genetic susceptibility testing include:

- Women diagnosed with breast cancer prior to age 45
- Women diagnosed with ovarian cancer
- Women with a family pedigree suggesting familial breast or ovarian cancer
- Blood relatives of those who carry a BRCA1 or BRCA2 mutation

(applicable to men or women).

Source:

Biesecker B, Boehnke M, Calzone K, et al. Genetic counseling for families with inherited susceptibility to breast and ovarian cancer *JAMA* 1993;269:1970-1974. (Published erratum appears in *JAMA* 1993;270:839.)

Issues Pertinent to Genetic Testing

- **The need for high-quality testing**
- **Informed consent**
- **Mechanisms for confidentiality**
- **Counseling both pre and post test**
 - **Life and health insurance**
 - **Employability**
 - **Psychological & ethical issues**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

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Factors that need to be considered before advising a woman to undergo genetic testing include the following:

- High-quality testing is necessary
- Informed consent is mandatory and those unable to give consent are ineligible for testing.
- Confidentiality must be maintained
- The woman will need pre and post test counseling, which should include the reality that potential exists for discrimination with life insurance, health insurance, and employability, and that potential exists for the development of profound psychological, emotional, and ethical issues for the patient and her family.

Genetic testing is an extremely personal issue and testing should never be recommended, but instead the issue presented as one of informed choice.

Source:

Ostrer H, Allen W, Crandall LA, et al. Insurance and genetic testing: Where are we now? *Am J Hum Genetics* 1993;52:565-577.

Options for High-Risk Women:

- **Lifestyle prevention strategies**
- **Increased surveillance**
- **Tamoxifen**
- **Prophylactic surgery**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 51

Whether she chooses to be tested, and whether she tests positively or not, there are several possible options for a woman at high risk for breast cancer. These include preventive lifestyle strategies, increased surveillance, the use of tamoxifen, and prophylactic surgery.

Sources:

1. Burke W, Daly M, Garber J, et al. Recommendations for follow-up care of individuals with an inherited predisposition to cancer. II BRCA1 and BRCA2. Cancer Genetics Consortium. *JAMA* 1997;277:997-1003.
2. Fisher B, Constantino JP, Wickerham DL, et al. Tamoxifen for prevention of breast cancer: Report of the National Surgical Adjuvant Breast and Bowel Project P-1 study. *J Natl Cancer Inst* 1998;90:1371-1388.

Options In Women at High Risk for Breast Cancer

Lifestyle Prevention *Strategies/Considerations*

- **Exercise, maintenance of ideal body weight**
- **Reproductive Choices:**
 - Use of estrogen-containing contraceptives
 - Age at first birth
 - Lactation
- **Diet**
 - High fiber?
 - Phytoestrogens?
 - Dietary fat – role doubtful
 - Alcohol
- **Menopause**
 - HRT Use

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 52

Many lifestyle issues are pertinent to breast cancer risk, some of which compete with other issues in women's health and some of which do not. We have reviewed the concept of endogenous and exogenous estrogen exposure in previous slides. There is some evidence that exercise can decrease the risk of premenopausal breast cancer and that maintenance of ideal body weight can decrease the risk of postmenopausal breast cancer. Diet is currently being investigated. Low fat diet has long been studied with little evidence for benefit. High-fiber diets may be beneficial, and there is early evidence that dietary phytochemicals, present in soy products and some fruits and vegetables, may be helpful. Avoidance of alcohol is thought to decrease risk, but this needs more investigation, especially as it pertains to overall mortality.

Source:

Brinton, LA. Ways that women may possibly reduce their risk of breast cancer. *Breast Diseases: A Year Book Quarterly* 1995;6:152-154

Options for High-Risk Women: Surveillance

- **Annual mammogram**
- **CBE every 6 - 12 months
depending on risk status**
- **Monthly BSE**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University. 1999.

SLIDE 53

For patients at high risk, recommendations for surveillance include:

- Annual mammography starting at the age at which high risk is identified, but not before age 25
- Clinical breast examination every 6 - 12 months, depending on risk status
- Breast self examination monthly.

We will discuss these recommendations in more detail later.

Source:

Garber JE, Smith BL. Management of the high risk and the concerned patient. In: Harris JR, Lippman ME, Morrow M (Eds). Lippincott - Raven. 1996, pp 335-341.

Options for High-Risk Women: **Tamoxifen**

- **Tamoxifen Prevention Trial**
- **49% reduction in breast cancer risk overall**

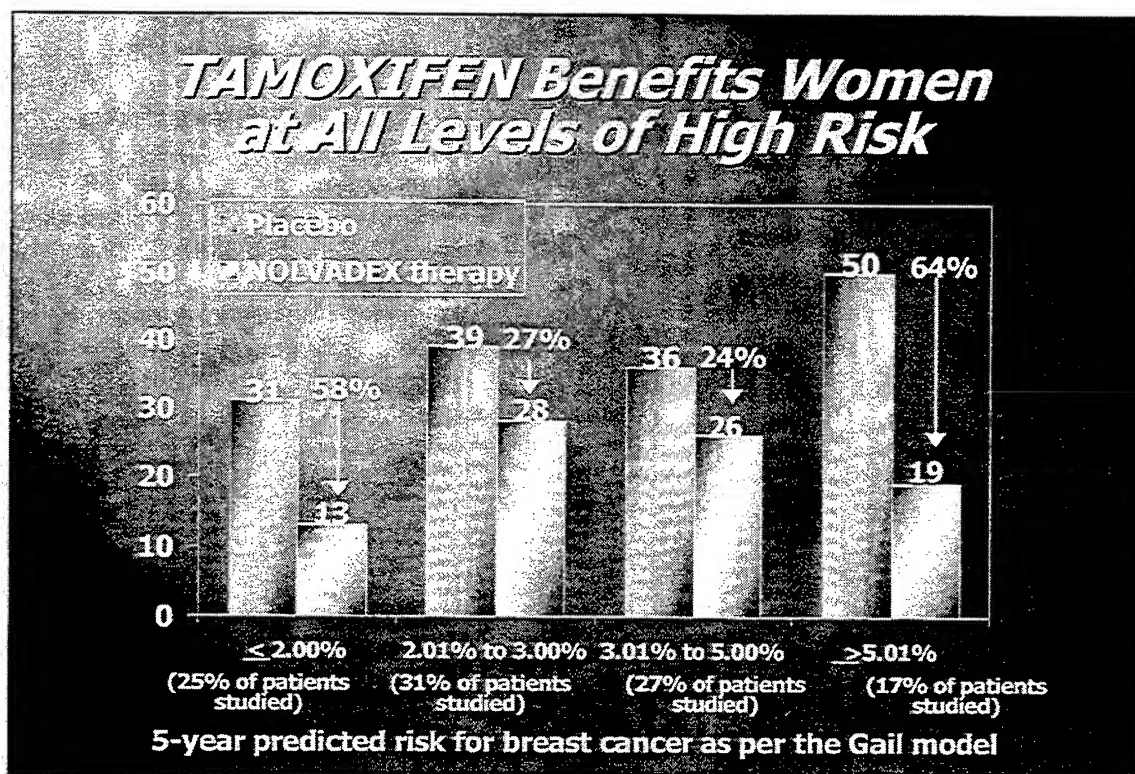
Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 54

Another option that should be considered for high-risk women is Tamoxifen use. The P-1 trial of the National Surgical Adjuvant Breast Project (NSABP), published in 1998, recruited over 13,000 women at high risk for breast cancer and demonstrated a statistically significant 49% overall reduction in breast cancer risk in women who used 20 mg per day of Tamoxifen for 5 years. It should be emphasized that Tamoxifen should not be used for low or even moderate-risk women. A trial from Italy failed to demonstrate any beneficial effects of Tamoxifen in this group. Another trial from England that studied women with a family history of breast cancer randomized to Tamoxifen versus placebo also demonstrated no benefit, but only about 2500 women were recruited and the power to test a difference was too low to draw conclusions from this study. The Italian study had twice as many participants but also suffered from low power in their analysis. Nonetheless, Tamoxifen is currently indicated only for those at high risk. In a few minutes we will be using the tools that have been created by the National Cancer Institute for determining risk in an individual woman.

Sources:

1. Fisher B, Constantino JP, Wickerham DL, et al. Tamoxifen for prevention of breast cancer: Report of the National Surgical Adjuvant Breast and Bowel Project P-1 study. *J Natl Cancer Inst* 1998;90:1371-1388.
2. Powles T, Eeles R, Ashley S, et al. Interim analysis of the incidence of breast cancer in the Royal Marsden Hospital tamoxifen randomized chemoprevention trial. *Lancet* 1998; 352:98-101.
3. Veronisi U, Maisonneuve P, Costa A, et al. Prevention of breast cancer with tamoxifen: preliminary findings of the Italian randomized trial among hysterectomized women. Italian Tamoxifen Prevention Study. *Lancet* 1998; 352:93-97.



Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999. Modified from the Nolvadex Patient Counseling Card. AstraZeneca Pharmaceuticals, Wilmington, DE, 1999. Used with permission.

SLIDE 55

Remember that to be eligible for the Tamoxifen Prevention Trial, the 5-year predicted absolute risk for breast cancer had to be at least 1.67%. The patients are being advised that a 5-year predicted absolute risk of 1.7% is the risk figure at which they should consider Tamoxifen use. The P-1 study demonstrated risk reductions for all levels of high risk, ranging from 24 to 64%. Note on the far left section of the graph that women with a 5-year absolute-risk of 2% or less had a 58% reduction in risk. These figures refer to incidence; there have been no mortality reduction benefits to date, but the time on trial has not been long enough to assess this endpoint with any degree of accuracy.

Sources:

1. Fisher B, Constantino JP, Wickerham DL, et al. Tamoxifen for prevention of breast cancer: Report of the National Surgical Adjuvant Breast and Bowel Project P-1 study. *J Natl Cancer Inst* 1998;90:1371-1388.
2. NOLVADEX prescribing information. AstraZeneca Pharmaceuticals, Wilmington, DE.

Health Effects in NSABP P-01 Trial

	<u>#Cases /1000 Women Annually</u>	
	<u>Tamoxifen</u>	<u>Placebo</u>
Breast Cancer	3.58	6.49*
Hip fractures	0.38	0.84
Wrist fractures	2.91	3.11
Ischemic Heart Disease	2.57	2.47

** = Statistically significant*

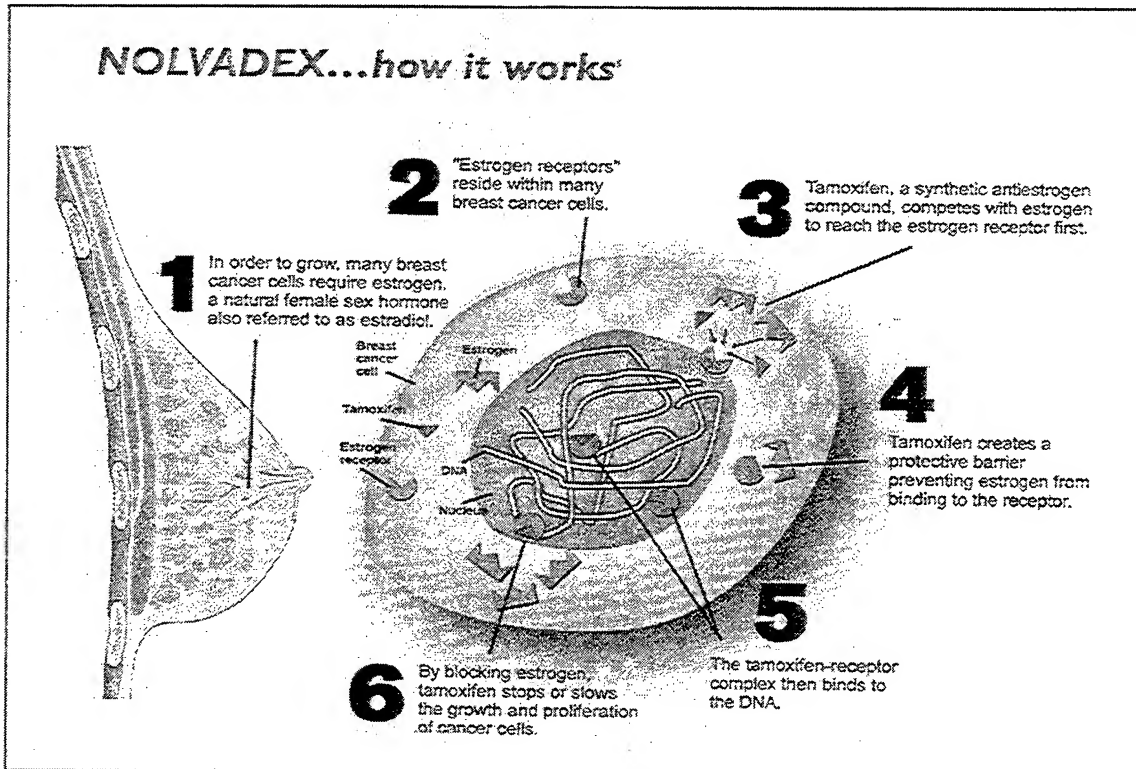
Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 56

In the trial, health effects of Tamoxifen were studied for diseases other than breast cancer. It was initially hoped that Tamoxifen might reduce the risk of cardiovascular disease and osteoporosis. However, there was no effect of Tamoxifen on risk of ischemic heart disease, and although the risk of fracture was lessened in the Tamoxifen group, this result was not statistically significant.

Source:

Fisher B, Constantino JP, Wickerham DL, et al. Tamoxifen for prevention of breast cancer: Report of the National Surgical Adjuvant Breast and Bowel Project P-1 study. *J Natl Cancer Inst* 1998;90:1371-1388.



Slide Credit: From Nolvadex Patient Counseling Card. AstraZeneca Pharmaceuticals, Wilmington DE, 1999. Used with permission.

SLIDE 57

This slide illustrates one mechanism by which Tamoxifen is thought to work.

Tamoxifen, which is an anti-estrogen, competes with estrogen for binding to the estrogen receptor. When the estrogen receptor is bound by Tamoxifen instead of estrogen, this complex inhibits the proliferation of cancer cells which would otherwise occur in the presence of estrogen.

Source:

Fisher B, Constantino JP, Wickerham DL, et al. Tamoxifen for prevention of breast cancer: Report of the National Surgical Adjuvant Breast and Bowel Project P-1 study. *J Natl Cancer Inst* 1998;90:1371-1388.

Tamoxifen Counseling:

Contraindications based on Lifestyle

Pregnancy, lactation

Hormonal contraception

Hormone replacement therapy

Contraindications based on Medical History

Current anticoagulant therapy

History of DVT, PE, Stroke

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 58

The recommended treatment dose for breast cancer prevention is 20 mg of Tamoxifen every day for 5 years. This should be an uninterrupted course, so a woman should be told to use birth control during this 5 year time period. In addition, the teratogenic effects of Tamoxifen have not been studied and use during pregnancy and lactation is contraindicated. Since hormone-containing birth control methods have a mechanism of action which involves the estrogen receptor, barrier methods of contraception should be used. For similar reasons, HRT use is discouraged while a woman is taking Tamoxifen. HRT use after a 5-year course of Tamoxifen is acceptable. Contraindications to Tamoxifen therapy based on medical history include current use anticoagulant therapy, or a history of deep-vein thrombosis, pulmonary embolism or stroke.

Sources:

1. Fisher B, Constantino JP, Wickerham DL, et al. Tamoxifen for prevention of breast cancer: Report of the National Surgical Adjuvant Breast and Bowel Project P-1 study. *J Natl Cancer Inst* 1998;90:1371-1388.
2. Nolvadex Patient Counseling Card. AstraZeneca Pharmaceuticals, 1999, Wilmington, DE.

Tamoxifen Counseling: Side Effects

	<u>#Cases / 1000 Women Annually</u>	
	<u>Tamoxifen</u>	<u>Placebo</u>
Endometrial CA	2.3	0.9*
Venous thromboembolism	1.3	0.8
Pulmonary embolism	0.7	0.2*
Stroke	1.5	0.9
Cataracts	24.8	21.7*
	<u>Frequency in Participants</u>	
Hot flashes	80%	68%
Vaginal discharge	55%	35%
	<i>* = Statistically significant</i>	

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 59

The side effects of Tamoxifen are those listed. Tamoxifen has an estrogenic effect on the uterus and in the P-1 study, there was 2.5 times the incidence of endometrial carcinoma in the Tamoxifen group as compared with the placebo group overall. The increased incidence was not observed in premenopausal women and was 4.0 for the postmenopausal group. All women with endometrial carcinoma randomized to the Tamoxifen arm were diagnosed with Stage I disease. There is a significantly increased risk of pulmonary embolism and cataracts in women on Tamoxifen. Risk was increased for deep-vein thrombosis and stroke, although those were not statistically significant. Less serious but much more frequent side effects of Tamoxifen include hot flashes and vaginal discharge, both of which were elevated in the Tamoxifen group.

Sources:

1. Fisher B, Constantino JP, Wickerham DL, et al. Tamoxifen for prevention of breast cancer: Report of the National Surgical Adjuvant Breast and Bowel Project P-1 study. *J Natl Cancer Inst* 1998;90:1371-1388.
2. Nolvadex Patient Counseling Card. AstraZeneca Pharmaceuticals. 1999. Wilmington, DE.

Options for High-Risk Women: Prophylactic Surgery

- **Bilateral Mastectomy**
- **Bilateral oophorectomy if
BRCA-1, BRCA-2 positive**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 60

The option of prophylactic surgery is complicated. If a woman tests positively for a genetic mutation, options will need to include a discussion of consideration for bilateral oophorectomy in addition to bilateral mastectomies. Women should be made aware that while prophylactic surgery markedly decreases risk, it does not eliminate it with 100% certainty. For high risk women based on family history, but who have not had genetic testing, 1 case of breast cancer is prevented for every 6 undergoing bilateral prophylactic mastectomy, and 1 death prevented for every 25 undergoing the procedure. Prophylactic surgery is a highly personal decision and should include counseling in a specialty setting. Making a recommendation for prophylactic surgery is strongly discouraged; instead, high-risk women should be encouraged to become as educated as possible about their options.

Sources:

1. Schrag D, Kuntz KM, Garber JE et al. Decision analysis, effects of prophylactic mastectomy and oophorectomy on life expectancy among women with BRCA-1 or BRCA-2 mutations. *NEJM* 1997; 336:1465-1471.
2. Hartmann LC, Schaid DJ, Woods JE et al. Efficacy of bilateral prophylactic mastectomy in women with a family history of breast cancer. *NEJM* 1999;340:77-84



Breast Cancer Screening and Evidence-Based Medicine

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 61

Because we have clues but no definitive answers to the primary prevention of breast cancer, we currently must depend on secondary prevention--that is, screening--to achieve maximum cancer control. But there are risks as well as benefits to any screening effort. Who should be screened? How often? Should screening be curtailed at some point? This section of the curriculum will address these issues.

Evaluation Criteria for Screening

- **Burden of suffering significant**
- **Latent period of disease of sufficient length**
- **Diagnosability during latent stage**
- **Early intervention changes outcome**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 62

Any screening test is subject to well-established evaluation criteria. These include:

- The disease burden is significant
- The natural history of the disease includes a latent period of sufficient length
- The disease can be diagnosed during the latent period using the screening test
- The outcome of the disease can be changed through application of the screening test

We will discuss each of these as they relate to screening with mammography.

Source:

Cole P, Morrison AS. Basic issues in cancer screening. In: Miller AB (ed). *Screening in Cancer*. Vol 40. Geneva: UICC, 1978:7.

Breast Cancer: **Burden of Disease**

<u>AGE GROUP</u>	<u>PERCENTAGE</u>	<u># / 1000</u>
<40	6.5%	0.03
40 - 49	16.0%	1.60
50 - 59	17.0%	2.50
60 - 69	24.0%	3.80
70 - 79	23.0%	4.30
80 - 89	13.0%	4.10

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

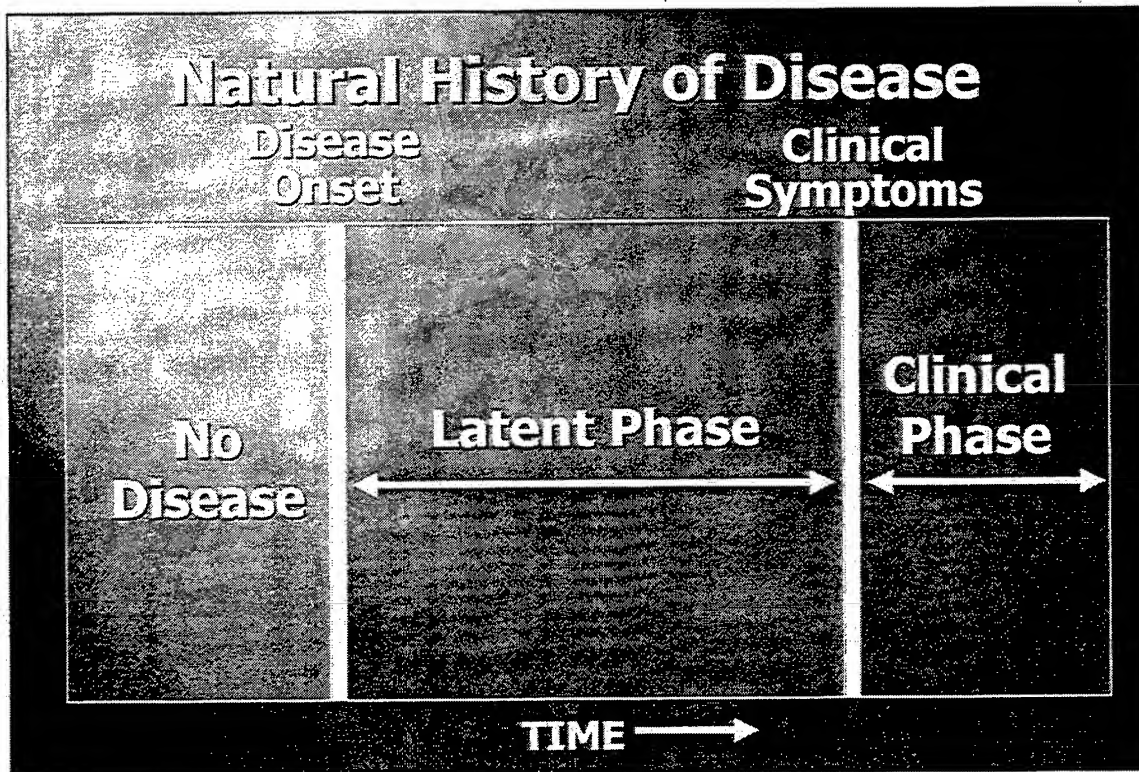
SLIDE 63

There is no debate that breast cancer is a significant public health problem. This slide demonstrates the frequency in percentage of breast cancer cases diagnosed by age group.

The burden of disease begins about age 25, and escalates after that. Although breast cancer incidence increases with age, the percentage of women diagnosed by age reflects the uneven distribution of age groups in the population. Breast cancer is the most common cause of mortality for any reason for the 35-54 age group.

Source:

Reis LAG, Miller BA, Hankey BF et al. (eds): SEER Cancer Statistics Review, 1973-1991: Tables and Graphs. Bethesda, MD: National Cancer Institute. NIH Pub. No. 94-2789, 1994:116-135.



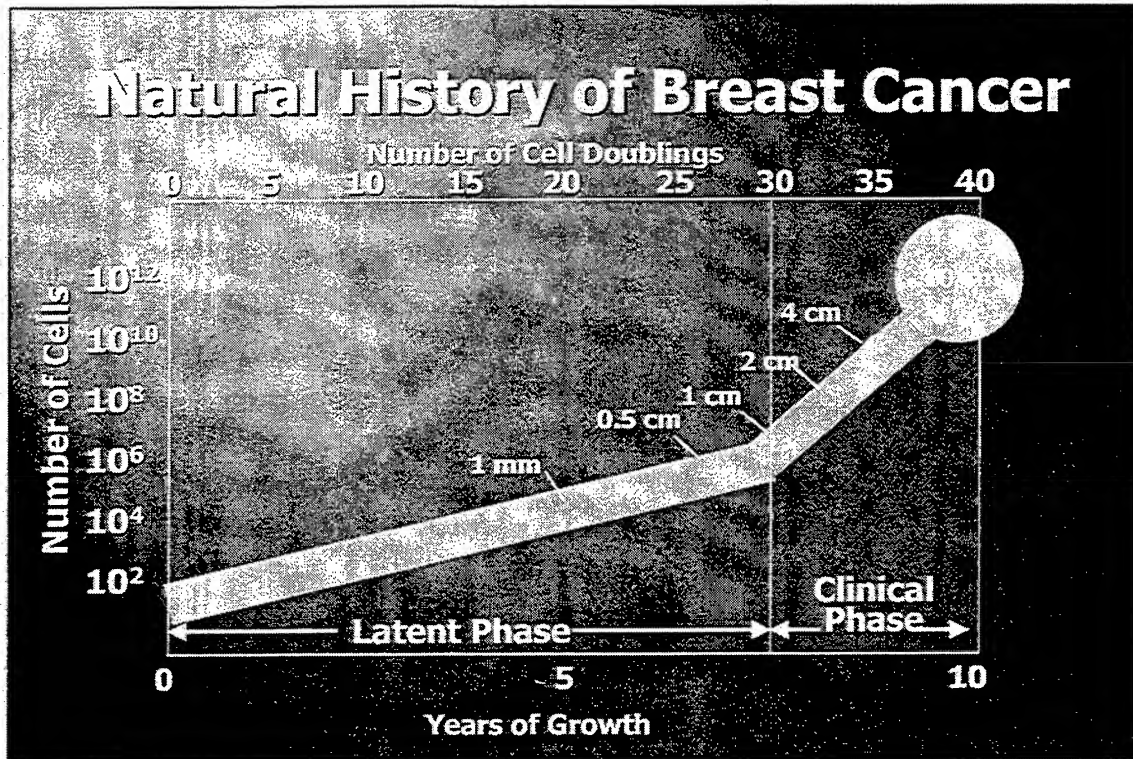
Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 64

Before addressing the next criteria for screening for breast cancer, we must briefly discuss the natural history for any disease. This slide plots out phases in a disease process. The latent phase of a disease refers to the period of time from the onset of exposure to the clinical manifestation of the disease. In infectious diseases, this is typically quite short, a matter of hours or days. For cancer, the latent period is usually months or years. The clinical phase of disease represents the symptomatic phase, which also encompasses months or years for breast cancer.

Source:

Last JM (ed). *A Dictionary of Epidemiology*. New York, NY: Oxford University Press, 1995.



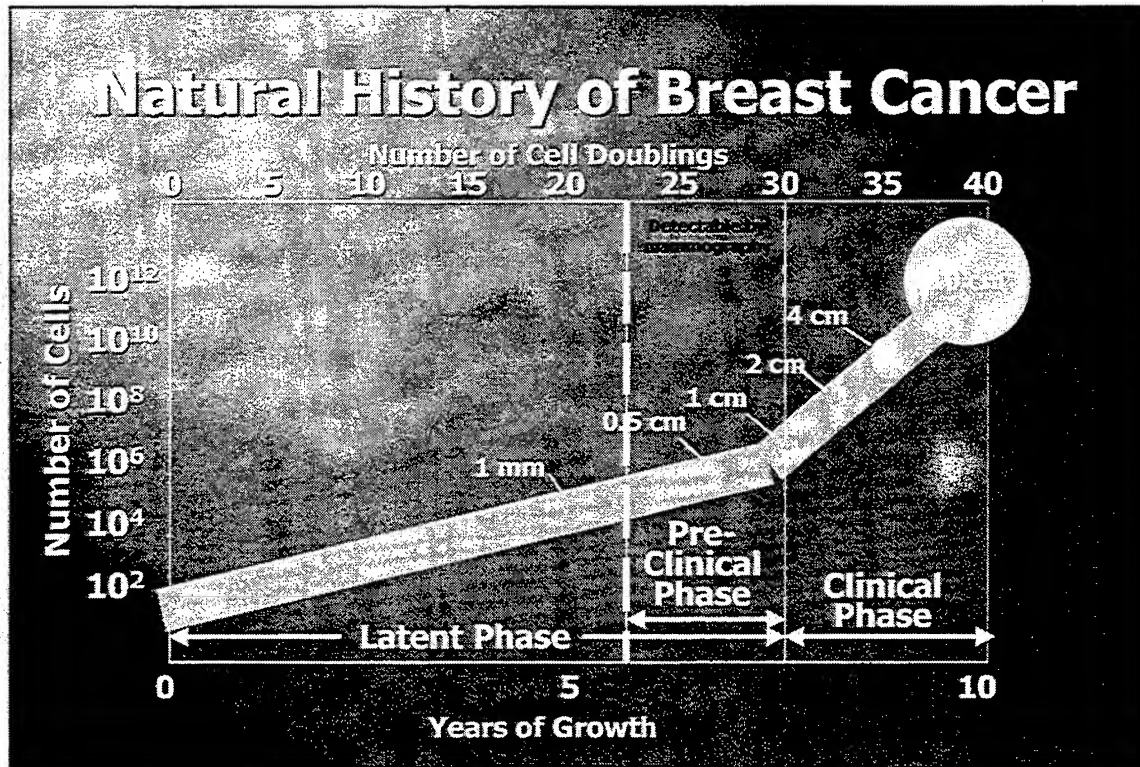
Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999. Modified from Nolvadex Patient Counseling Card. AstraZeneca Pharmaceuticals, Wilmington DE, 1999. Used with permission.

SLIDE 65

This slide demonstrates the natural history of breast cancer. In general, the doubling time for breast cancer averages about 100 days. This means that it takes 100 days for one cell to become two, two to become four, and so on. By the time that a tumor is one centimeter in size, it contains over 1 billion cancer cells and may be palpable. It averages 8 years between the onset of disease and the time that cancer growth reaches one centimeter. This period represents the latent phase of tumor growth. Because of the length of the latent phase for breast cancer, application of a screening test is theoretically possible.

Sources:

1. Harris JR, Hellman S. Natural history of breast cancer. In: Harris JR, Hellman S, Henderson IC, et al. (Eds.) *Breast Diseases*. 2nd ed. Philadelphia, PA: JB Lippincott Company; 1991:165-181.
2. Collins VP, Loeffler RK, Tivey H. Observations on growth rates of human tumors. *Am J Roentgenol*. 1956;76:988-1000.
3. Fisher B. The evolution of paradigms for the management of breast cancer: A personal perspective. *Cancer Res*. 1992;52:2371-2383.



Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999. Modified from Nolvadex Patient Counseling Card. AstraZeneca Pharmaceuticals, Wilmington DE, 1999. Used with permission.

SLIDE 66

For a screening test to be effective, that test must be capable of diagnosing disease prior to it becoming symptomatic. That is, it must be capable of disease detection during the latent phase. Mammography is capable of detecting breast cancer in asymptomatic women and therefore meets this criteria. As shown by the middle portion of the graph, the portion of the latent phase during which breast cancer is detectable by mammography is termed the pre-clinical phase. We will discuss this further in future slides.

The last and most important criteria in the evaluation of a screening test evaluates if outcome is effected.

Sources:

1. Harris JR, Hellman S. Natural history of breast cancer. In: Harris JR, Hellman S, Henderson IC, et al. (Eds.) *Breast Diseases*. 2nd ed. Philadelphia, PA: JB Lippincott Company; 1991:165-181.
2. Collins VP, Loeffler RK, Tivey H. Observations on growth rates of human tumors. *Am J Roentgenol*. 1956;76:988-1000.
3. Fisher B. The evolution of paradigms for the management of breast cancer: A personal perspective. *Cancer Res*. 1992;52:2371-2383.

Screening Mammography: *Does Early Intervention Effect Outcome?*

■ **Efficacy**

■ **Effectiveness**

■ **Efficiency**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 67

There are three pertinent terms to understand in the evaluation of the outcome of a screening intervention.

First is efficacy, meaning “can it work”? This question is answered through randomized clinical trials.

The second is effectiveness, meaning “does it work”? This refers to the applicability of the intervention in the general population and includes issues of feasibility, availability, compliance, etc. It is answered through observational studies.

The third is efficiency, or “is it worth doing”? This considers the benefit risk ratio, costs to individuals, and costs to society.

Source:

Last JM. *A Dictionary of Epidemiology*. New York, NY: Oxford University Press, 1995.

Efficacy **in Screening Mammography**

Women aged 50 and over:

**Average 30% mortality reduction
in 8 prospective/ randomized controlled
clinical trials**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 68

The gold standard for evaluating screening efficacy is mortality reduction within the context of a prospective controlled, randomized trial. Death is an easily measured outcome that is not subject to the biases inherent in the measurement of other endpoints. Mammography has been studied in asymptomatic women in at least eight randomized, controlled prospective clinical trials. An average 30% mortality reduction has been demonstrated in each of these trials for women 50-74 years old. Translating this to the entire U.S. population theoretically could result in a reduction in breast cancer deaths from 46,000 per year to approximately 32,000 per year. This assumes that none of the 46,000 were screened prior to their diagnosis.

Source:

Shapiro S. Screening: Assessment of current studies. *Cancer* 1994;74:231-238.

Efficacy **in Screening Mammography**

Women aged 40-49:

Meta-Analysis 1997:

18% mortality reduction

RCT:

Malmo: 36% mortality reduction

Gothenberg: 44% mortality reduction

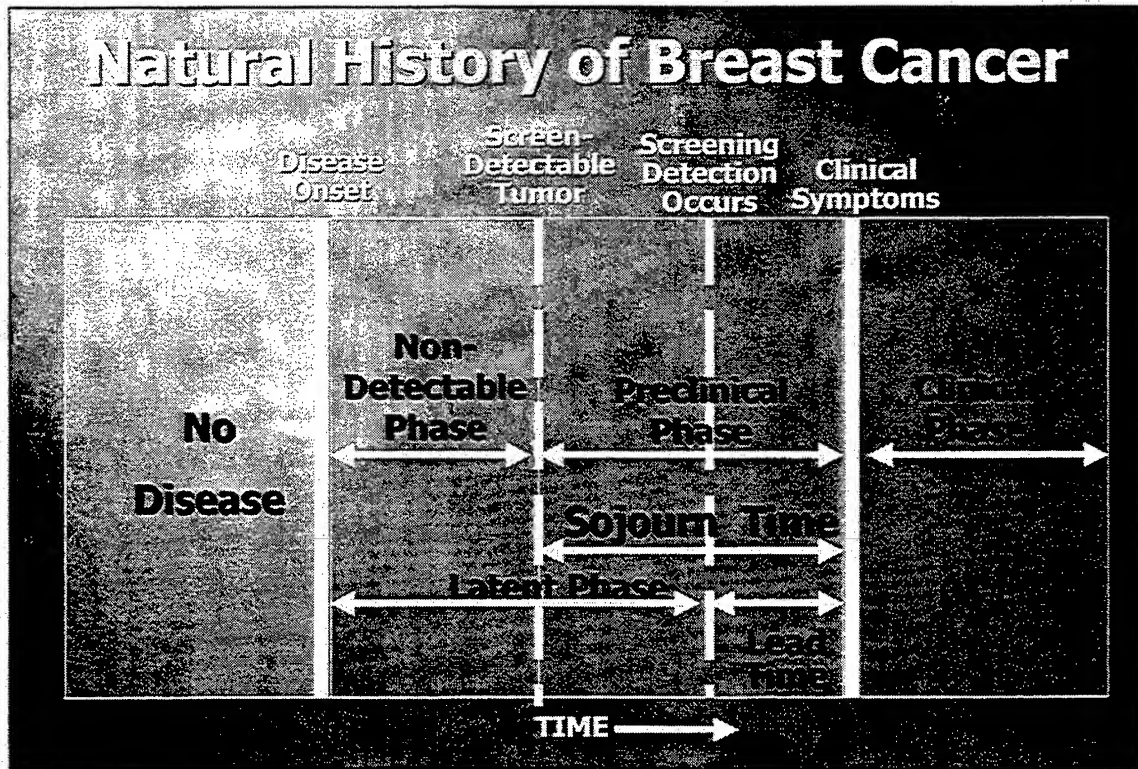
Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 69

The efficacy of screening mammography for women in their forties has generated much debate. In 1997, a meta-analysis of eight controlled prospective clinical trials demonstrated a statistically significant mortality reduction of 18% in this groups of women. The results of two individual Swedish randomized trials also were published that year, demonstrating a 36% and 44% mortality reduction, respectively. In 1999, however, a 14 year follow-up from the Edinburgh randomized controlled trial showed no benefit in women less than 50. This contrasted with findings from the UK, where 16 – year follow up results from a non-randomized study showed a 35% mortality reduction in screened women in all age groups between 45 and 64 years. A randomized controlled trial is currently being conducted in the UK of women 40 - 41 to try to resolve the controversey. Results are not yet available.

Sources:

1. Hendrick RE, Smith RA, Rutledge JH, et al. Benefit of screening mammography in women aged 40-49: A new meta-analysis of randomized controlled trials. *J Natl Cancer Inst Monogr* 1997;22:87-92.
2. Bjurstam N, Bjorneld L, Duffy SW, et al. The Gothenburg breast screening trial: First results on mortality, incidence, and mode of detection for women ages 39-49 years at randomization. *Cancer* 1997;80:2091-2099.
3. Andersson I, Janzon L. Reduced breast cancer mortality in women under age 50: Updated results from the Malmo Mammographic Screening Program. *J Natl Cancer Inst Monogr* 1997;22:63-67.
4. 16-year mortality from breast cancer in the UK Trial of Early Detection of Breast Cancer. *Lancet* 1999; 353:1909-1914.
5. Alexander FE, Anderson TJ, Brown HK, et al. 14 years of follow-up from the Edinburgh randomised trial of breast-cancer screening. *Lancet* 1999; 353:1903-1908.
6. Moss S. A trial to study the effect on breast cancer mortality of annual mammographic screening in women starting at age 40. Trial Steering Group. *J Med Screen* 1999; 6:144-148.



Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 70

This finding of efficacy in women 40-49 was dependant on follow-up times of about 8 years as opposed to 5 years for women 50 and over. To explain this, an understanding of the meaning of sojourn time and lead time is necessary. Remember that the latent phase of a tumor consists of a non-detectable phase and a preclinical phase, during which the disease is potentially detectable. The application of screening shifts the definition of the latent phase, so that it ends at the point at which the disease becomes potentially detectable through screening, even though it remains asymptomatic. The time during which the disease is potentially detectable in an asymptomatic individual is called the sojourn time and corresponds to the preclinical phase of disease. Lead time represents the length of time from disease detection using screening to the time that symptoms would have occurred had screening not occurred.

Source:

Feig SA. Estimation of currently attainable benefit form mammographic screening of women aged 40-49 years. *Cancer* 1995;75:2412-2419.

Screening Mammography and **SOJOURN TIME**

PROBLEM

Shorter sojourn time in women 40-49
= increased interval cancer rate
= decreased efficacy of screening

CONCLUSION

Screening every 24 months for young women not as effective as for older ones as screening interval exceeded mean sojourn time

SOLUTION

Screen women 40-49 yearly

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 71

Women 40-49 have been shown to have a greater frequency of aggressive tumors with shorter sojourn times or shorter preclinical phases than in women 50 and over. This leads to an increased interval cancer rate, meaning an increased frequency of symptomatic tumors appearing between screens. This results in decreased efficacy of screening. The solution to this important problem is to decrease the screening interval to exceed the mean sojourn time. Application of this principle leads to the recommendation for annual mammography screening in this age group.

Source:

Feig SA. Estimation of currently attainable benefit from mammographic screening of women aged 40-49 years. *Cancer* 1995;75:2412-2419.

Effectiveness of Breast Cancer Screening

National Breast and Cervical Cancer Early Detection Program

- **1991 - 1995 multicenter project**
- **230,143 women screened**
- **1,141 patients diagnosed with breast cancer**
- **50 - 59% of breast cancer stage I or in-situ**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 72

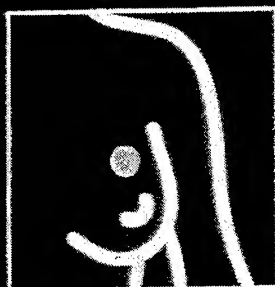
Now that we have concluded that screening mammography can work in the clinical trial setting, we need to evaluate whether it does work in the community setting. The most recent study to demonstrate screening mammography effectiveness is the National Breast and Cervical Cancer Early Detection Program, a congressionally mandated program for low-income women conducted by the Centers for Disease Control. In this project, all goals of the Quality Determinants of Mammography guidelines panel were met, and 50-59% of the cancers diagnosed were stage 0 or I. Although successful at detecting incident cancers in early stages, optimal effectiveness has been compromised by low compliance with rescreening.

Source:

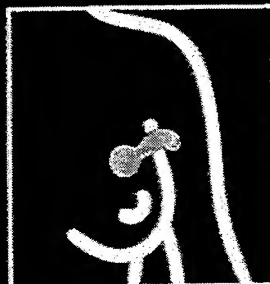
May DS, Lee NC, Nadel MR et al. The National Breast and Cervical Cancer Early Detection Program: Report on the first 4 years of mammography provided to medically underserved women. *AJR* 1998;170:97-104.

BREAST CANCER PATHOLOGIC STAGING

STAGE I



STAGE II



STAGE III



STAGE IV



AJCCS. 1977

Slide Credit: from Breast Cancer Speaker's Kit. AstraZeneca Pharmaceuticals, Wilmington, DE. Used with permission.

SLIDE 73

This is a good time to discuss breast cancer staging. Stage 0 refers to carcinoma-in-situ. In this form of cancer, the tumor cells are confined to the cells themselves and have not spread beyond the basement membrane. Except in unusual circumstances, they do not have the biological capacity for metastasis.

Stage I refers to the presence of a tumor measuring 2 cm or less with no lymph node metastasis. Both criteria must be met for the diagnosis of stage I disease.

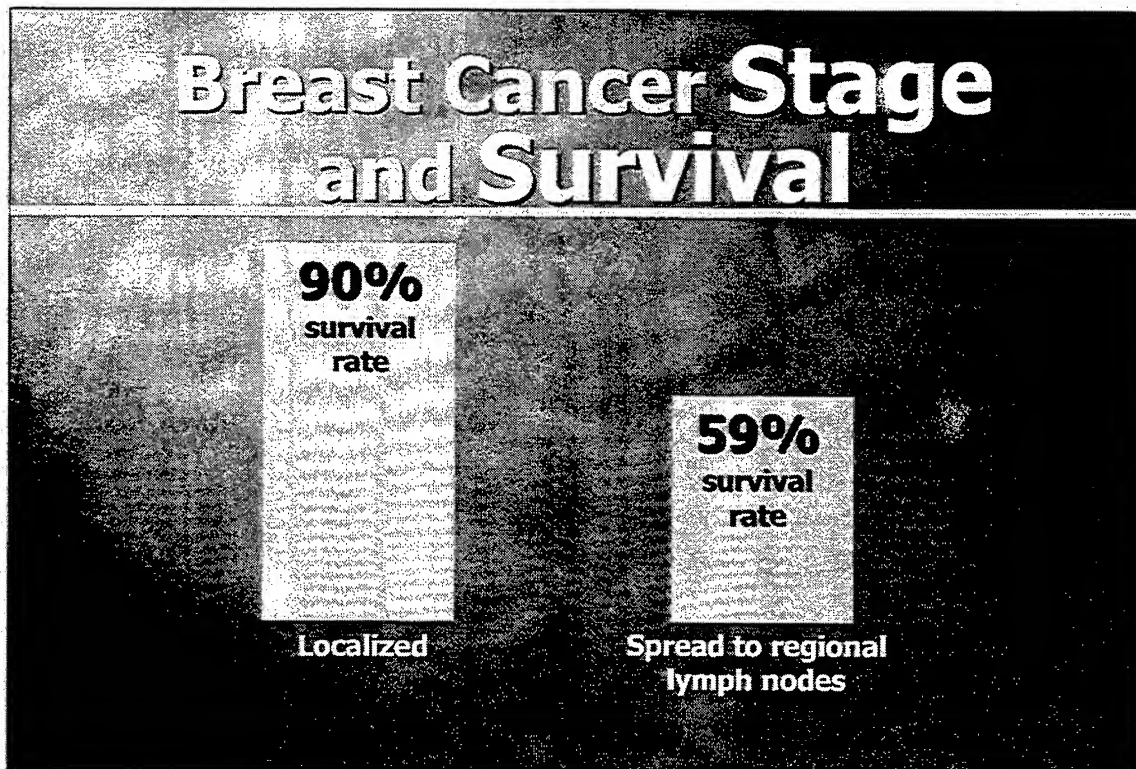
If the tumor is larger than 2 cm, or a patient has positive lymph nodes, she is classified as stage II or above.

Stage III disease implies locally advanced breast cancer, usually involving the skin or chest wall.

Stage IV refers to the presence of metastatic disease. The most common distant sites of metastases include the lung, liver, bones, and brain.

Source:

American Joint Committee on Cancer: *Manual for Staging of Cancer*. 4th ed. Philadelphia, PA: J.B. Lippincott, 1992, pp. 149-154.



Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000. Modified from a slide from the American Cancer Society, Public Domain.

SLIDE 74

Survival rates are most commonly quoted as 5-year survival by stage. The 5-year survival of stage I disease is over 90%, and for stage 0, approaches 100%. On the other hand, if there is spread to the regional lymph nodes, 5-year survival can be below 60%. Mammography is capable of diagnosing cancer in earlier stages than are possible with CBE alone. This leads to earlier stage at diagnosis and improved survival.

Source:

National Cancer Institute. Division of Cancer Prevention and Control. 1987 Annual Cancer Statistics Review. Including Cancer Trends 1950-1985. NIH Publication No. 88-2789. Bethesda, MD: National Institutes of Health, 1988.

Efficiency of Breast Cancer Screening with Mammography

Benefits

- **mortality reduction**
- **downstaging of disease**
- **increased treatment options**
- **decreased cost and morbidity of treatment**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 75

One of the most important criterion for the evaluation of screening worth is efficiency, "is it worth doing?" We have discussed screening benefits related to mortality reduction, and down-staging of disease. Smaller tumors at diagnosis also imply more treatment options and decreased cost and morbidity of treatment.

Source:

Hurley SF, Kaldor JM. The benefits and risk of mammographic screening for breast cancer. *Epidemiol Rev* 1992; 14:101-130.

Risks **of Screening Mammography**

- **Overdiagnosis** of subclinical disease

- **False positive results**

 - Anxiety

 - Excess biopsies

- **False negative results**

 - Missed diagnosis of breast cancer

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 76

The risks of screening mammography include the risks of any screening procedure.

Overdiagnosis of subclinical disease precipitates treatment that may not benefit the patient. False positive results precipitate anxiety and an excess number of interventions and false negative results can delay the diagnosis of breast cancer. We will focus on this latter problem in the next module.

Sources:

1. Hurley SF, Kaldor JM. The benefits and risk of mammographic screening for breast cancer. *Epidemiol Rev* 1992; 14:101-130.
2. National Institutes of Health Consensus Development Panel. National Institutes of Health Consensus Development Conference Statement: Breast Cancer Screening for Women Ages 40-49, January 21-23, 1997. *J Natl Cancer Inst* 1997;89:1015-1026.

Risks of Screening Mammography (cont'd)

- **Discomfort**
- **Radiation Risk**
- **Cost**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 77

Other risks include discomfort, radiation risk and cost. Discomfort is a reality for many women and should be acknowledged and validated. Anecdotally, over-the-counter pain medicine taken 1 hour before the procedure has been helpful. The procedure should be scheduled in ovulating women during the follicular phase of the menstrual cycle in order to reduce discomfort and avoid suboptimal breast compression that can occur during the luteal phase. Each of these will now be discussed.

Risks of Screening Mammography: *Radiation Risk*

Hypothetical risk from extrapolated data:

**Number cases per 1 million women screened with
mammography at age 45:**

Theoretical #

Excess deaths

5

Number of deaths averted

225

**Estimates based on mammogram radiation dose of 0.25 rads/
2 view film/breast**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 78

Concern about excess breast cancer incidence from radiation exposure comes from studies showing increased risk from multiple chest fluoroscopies during treatment for tuberculosis in the 1920s and 1930s, and from studies of atomic bomb survivors in Japan. The doses delivered in these studies ranged from 100 to 1000 rads and the risk was greatest in adolescents and women in their early 20s in these studies. The average mammogram in the late 1990s delivers 0.25 rads per 2 view film per breast. Mammography may cause five excess deaths from breast cancer per 1 million women screened at age 45. However, 225 deaths theoretically are averted through screening. The benefits clearly outweigh the theoretical risks. For asymptomatic women less than age 40, routine mammography is not recommended unless risk status is extremely high. Symptomatic women will be discussed in a later section. Mammography is usually not done in women less than 30 years of age unless at extremely high risk, because the risk:benefit ratio is not favorable.

Source:

Feig SA, Dodd GD, Hendrick RE. Mammography risks and benefits. In: Poznanski AK (Ed). *Radiation Protection Twenty-Eight Annual Meeting of the National Council on Radiation Protection and Measurements*. Bethesda MD: National Council on Radiation Protection and Measurements, 1993, pp 240-253.

Risks of Screening Mammography:

Cost

- **Cost/yr life saved assuming 30% mortality reduction: \$6,000 - \$13,000**
- **Median costs per year of life saved in appropriate age groups:**

<u>Screening/Intervention</u>	<u>\$</u>
Cholesterol	6,000
Annual mammography	8,900
Cervical cancer	12,000
Seatbelts/Airbags	32,000
Hormone replacement therapy	42,000

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999. Modified from Feig SA. Mammographic screening of women aged 40-49 years. Benefit, risk, and cost considerations. *Cancer* 1995 Nov 15;76(10 Suppl):2097-2106.

SLIDE 79

The cost of screening is usually measured as cost per year of live saved. The quoted costs in this list by Feig are median costs per year of life saved. The mammography data includes annual mammography beginning at age 40. Other authors calculate other numbers, some of which are higher, especially for women 40 – 49. Nonetheless, no matter how the figures are calculated, annual mammography compares favorably with other interventions accepted in public health.

Sources:

Feig SA. Mammographic screening of women aged 40-49 years. Benefit, risk, and cost considerations. *Cancer* 1995 Nov 15;76(10 Suppl):2097-2106.

Salzmann P, Kerlikowske K, Phillips K. Cost-effectiveness of extending screening mammography guidelines to include women 40 to 49 years of age. *Ann Intern Med* 1997; 127:955-965.

Mammography Screening Guidelines

Normal Risk Women

<u>Age</u>	<u>AAFP</u>	<u>ACS, ACR</u>	<u>NCI</u>	<u>USPSTF</u>
40 - 49	Counsel	Annual	1-2 Yrs	NR*
50 - 69	1-2 Yrs	Annual	1-2 Yrs	1-2 Yrs
70 & over	NR*	Annual	1-2 Yrs	NR*

*NR = No Recommendation

AAFP = American Academy of Family Physicians
ACS = American Cancer Society
ACR = American College of Radiology
NCI = National Cancer Institute
USPSTF = United States Preventive Services Task Force

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 80

Recommendations for screening mammography in normal-risk women vary by organization. A summary of recommendations of leading organizations is listed here.

Every major organization recommends screening in women 50-69 at intervals of 1-2 years. Recommendations are inconsistent for women aged 40-49 and 70 and over.

Patients of all ages should be made aware of the benefits and risks of medical procedures but especially those related to screening.

Sources:

1. American Academy of Family Physicians: Summary of Recommendations for Periodic Health Examination. [Http://www.aafp.org/exam/app-d2.html](http://www.aafp.org/exam/app-d2.html)
2. American Cancer Society: Statement on Mammography Guidelines. [Http://www.pslgroup.com/dg/196ba.htm](http://www.pslgroup.com/dg/196ba.htm).
3. National Cancer Institute: PDQ®: Screening for Breast Cancer. [Http://cancernet.nci.nih.gov/clinpdq/screening_for_breast_cancer_physician.html](http://cancernet.nci.nih.gov/clinpdq/screening_for_breast_cancer_physician.html).
4. U.S. Preventive Services Task Force. [Http://www.ahcpr.gov/clinic/](http://www.ahcpr.gov/clinic/)
5. Feig SA, D'Orsi CJ, Hendrick RE, et al. American College of Radiology Guidelines for Breast Cancer Screening. *AJR Am J Roentgenol*. 1998;171:29-33.

Most Common *Barrier* Cited by Women for not having a Screening Mammogram:

***"My doctor didn't tell me
that I needed one."***

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

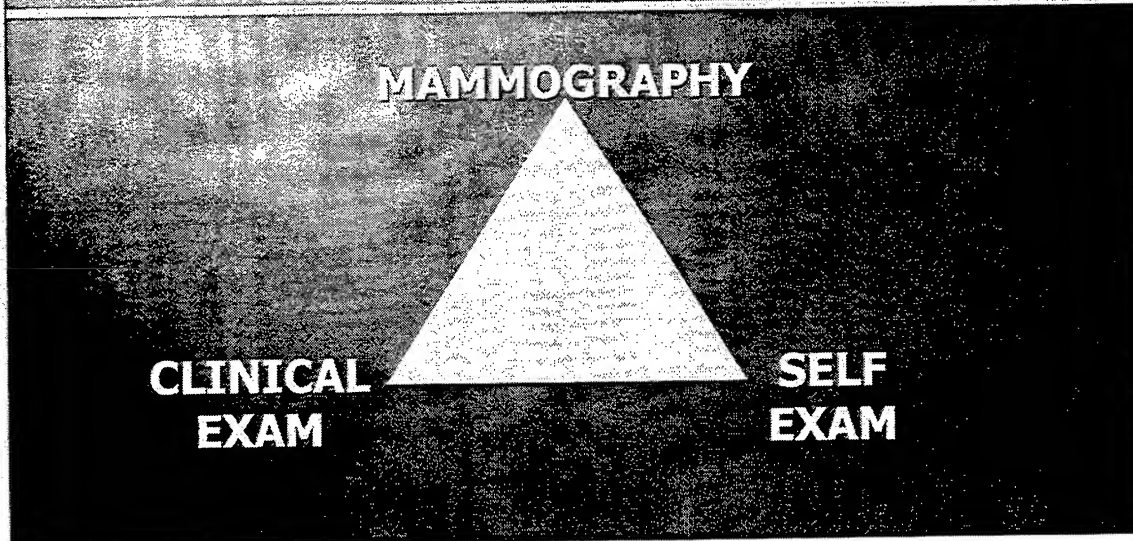
SLIDE 81

In multiple studies, the most common reason that women cite for not having a mammogram is that their doctor did not tell them that they needed one. Other reasons for underutilization of mammograms include: cost and/or lack of health insurance, and the misconception that without symptoms there is no need for mammography. Many studies have documented that older women are less likely to utilize mammography than younger women, and that physicians are less likely to recommend it. Although no randomized trials have been conducted in women older than 74, the exam is easier to interpret in elderly women whose breasts contain mostly adipose tissue because of the natural process of involution. Most organizations agree that as long as a woman would benefit from detection of breast cancer at an early stage, screening should continue. A recent case-control study of mammography in women over 65 years of age suggests a 45% reduction in mortality.

Sources:

1. Ackerman SP, et al. Cancer screening behaviors among U.S. women: Breast cancer 1987-1989, and cervical cancer, 1988-1989. *MMWR* 1992;41(55-2):17-34.
2. Dolan NC, Lee AM, McDermott MM. Age-related differences in breast carcinoma knowledge, beliefs, and perceived risk among women visiting an academic general medicine practice. *Cancer* 1997;1:413-420.
3. VanDijck JA, Verbeek AL, Beex LV, et al. Mammographic screening after the age of 65 years: Evidence for a reduction in breast cancer mortality. *Int J Cancer* 1996;66:727-731.

Triad of Breast Cancer Screening



Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 82

Breast cancer screening involves not only mammography but also clinical examination and breast self-examination. Clinical breast exam (CBE) has not been formally evaluated regarding its ability to reduce mortality from breast cancer separate from mammography, but the prevalence of breast disease and the complimentary role that it plays in the diagnosis of breast cancer make it an important part of the screening exam in asymptomatic patients. One recent large-scale study in a non-randomized setting shows a modest cancer detection rate with CBE alone, but mortality reduction was not evaluated. Its findings were consistent with those of CBE performance in mammography screening trials and will be discussed in detail in later sections of the curriculum. The last component of the breast cancer detection triad is breast self-examination.

Source:

Bobo JK, Lee NC, Thomas SF. Findings from 752 081 clinical breast examinations reported to a National Screening Program from 1995 through 1998. *J Natl Cancer Inst* 2000; 92:971-976.

Breast Self-Exam (BSE)

Randomized Studies:

1996 - St. Petersburg WHO Study:

No effect, poor compliance

1997 - Shanghai: No effect

Reasons to promote BSE:

- Reinforces provider-patient partnership
- Reinforces patient's role in her own health
- Encourages consultation with provider

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 83

Two randomized controlled trials recently examined the effectiveness of BSE at decreasing mortality from breast cancer. Neither had screening mammography available to its participants. A study in St. Petersburg, Russia begun in 1985 is inconclusive because only 18% of patients performed BSE at year 4. In Shanghai, 5-year data analysis shows no mortality reduction between the control and intervention arms.

Teaching our patients breast self-examination reinforces the partnership between the patient and the physician and the patient's role in breast cancer screening. Encouraging patients to perform BSE should be used to empower our patients. It should never be used as a tool to make patients feel guilty for undetected lumps. The purpose is to help women understand what their normal healthy breast feels like so that if anything changes, the patient will see a physician to find out if the change is of clinical significance.

Sources:

1. Thomas DB, Gao DL, Self SG et al. Randomized trial of breast self-examination in Shanghai: Methodology and preliminary results. *J Natl Cancer Inst.* 1997;89:355-365.
2. Semiglazov VF, Moiseenko VM, Protsenko SA et al. Preliminary results of the Russia (St. Petersburg) WHO program for the evaluation of the effectiveness of breast self-examination. *Vopr Onkol* 1996;42:49-55.

Breast Cancer Screening Guidelines: High Risk Women

- **Lobular carcinoma in-situ**
- **Atypical hyperplasia**
- **Strong family history**
- **Weak family history**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 84

Screening guidelines for high-risk women are not established, but expert opinion has generated a set of suggestions that can be followed. This can be found in appendix 1 of the manual.

Classification of **Breast Disease:**

■ **Malignant**

– **In-situ:** ductal or lobular

– **Invasive:** ductal or lobular

■ **Benign: ANDI**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 85

A basic classification divides breast disease into benign or malignant. Malignant disease classifications are logical: cancer can arise from lobules or ducts, presenting as invasive or in-situ disease. In contrast, confusion about the classification of benign disease is pervasive. Several terms are used to refer to the same condition, most being neither descriptive nor useful in directing the clinician to an effective management scheme. Normal physiologic processes in the breast are often described as “diseases”, which adds to the confusion and can be very frightening to patients. Hughes recently introduced the ANDI classification for benign disease - Aberrations of Normal Development and Involution.

Source:

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.), *Textbook of Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.

Benign Breast Disease: ANDI Classification

<u>DEVELOPMENT PHASE</u>	<u>AGE</u>
■ Early Reproductive Period	15-25
■ Mature Reproductive Period	25-40
■ Involutional Phase	35-55

Beyond Age 55: Little benign disease

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 86

The ANDI classification is logical, practical, and based on normal breast development. It considers age, classifying breast problems into 1 of 3 reproductive periods: early (ages 15-25), mature (ages 25-40) and involution (ages 35-55). Note that the classification ends at age 55; it is uncommon for a postmenopausal woman to have benign breast disease. This will be discussed in more detail later. A table of the common benign breast conditions can be found on page 2 of the appendix. It will be helpful to keep this classification in mind throughout the remainder of this presentation.

Source:

Aberrations of normal development and involution (ANDI): A concept of benign breast disorders based on pathogenesis. In: Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management*. London, 1989. Bailliere Tindall, 15-25.

Signs & Symptoms of Breast Disorders

- **Breast pain**
- **Non-palpable mammographic abnormalities**
- **Breast mass or asymmetrical thickening**
- **Nipple discharge**
- **Skin or nipple changes on observation**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 87

Breast disorders can be classified into one of five signs or symptoms. These include:

- Breast pain
- Non-palpable mammographic abnormalities
- Breast mass or asymmetrical thickening
- Nipple discharge
- Skin or nipple changes

We will discuss each in detail in the following sections.

Source:

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.). *Textbook of Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.

Signs & Symptoms of Breast Disorders

BREAST PAIN

- **Most common breast complaint**
- **Precipitates anxiety and worry**
- **Etiology often unknown**
- **Commonly hormonally-linked**
- **Self-limited in 80% - 85% of patients**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 88

Breast pain is the most common breast complaint, and in one large survey, 66% of women reported it. It is a symptom that can cause worry and anxiety about breast cancer. Unfortunately, the etiology is often unclear. The symptom is hormonally related in that it occurs most commonly 1 week prior to menses, and in some women taking hormone replacement therapy. Breast pain is self-limited in up to 85% of patients.

Source:

Maddox PR, Mansel RE. Management of breast pain and nodularity. *World J Surg* 1989;13:699-705.

BREAST PAIN **The Focused History**

- **Location**
- **Duration**
- **Unilateral/Bilateral**
- **Rank on 10-point scale**
- **Relation to hormones**
- **Lifestyle - altering**
- **Worry**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 89

The complaint of breast pain should be taken seriously. Ask about location, duration, and whether it is unilateral or bilateral. To assess the degree of discomfort, ask the patient to rank the pain on a 10-point scale. Establish if it is cyclic by asking if the pain changes with her menstrual cycle, and when appropriate, if it is related to hormone replacement therapy. Evaluate the degree to which it worries the patient, and whether it alters lifestyle by inquiring about interference with exercise, hugs, sexual activity, and sleep. Pay attention to areas of focal pain; many women with masses have their attention drawn to the area because of pain. If the pain is diffuse, reassure the patient. If it is lifestyle altering, it may be necessary to intervene. This will be discussed in more detail in a later slide.

Source:

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.), *Textbook of Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.

Breast Pain and Breast Cancer:

Cardiff Mastalgia Clinic: 1982

15% of cancer patients presented with breast pain, most of whom had breast masses on BSE

7% of cancer patients presented with mastalgia alone

- **Unilateral**
- **Localized**
- **Constant**
- **Persistent**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 90

The Cardiff Clinic reported on 240 cancer patients with operable breast cancer studied prior to the era of screening mammography. Fifteen percent had breast pain in addition to other symptoms. Seven percent had breast pain as their only presentation. In most of these, a mass was found on initial or subsequent CBE.

There is a low yield from diagnostic mammography when the sole symptom is breast pain, but screening mammography should be done according to the guidelines. Of women presenting with breast pain who have a normal CBE and radiologic studies, cancer will be found in about 0.5% on follow-up. This necessitates 3-6 month follow up exams in all women with persistent mastalgia.

Sources:

1. Preece PE, Baum M, Mansel RE, et al. The importance of mastalgia in operable breast cancer. *Br Med J* 1982;284:1299-1300.
2. Klimberg VS. Etiology and management of breast pain. In: Bland KI and Copeland EM (eds). *The Breast: Comprehensive Management of Benign and Malignant Disease*. Philadelphia, PA: W.B. Saunders Company, 1998, pp. 247-260.

Management of BREAST PAIN

- **Reassurance**
 - = no sign of breast cancer
 - = common symptom
 - = self-limited
- **Eliminate caffeine**
 - = may affect pain, but not nodularity or cancer
- **Supportive brassiere**
- **Lower estrogen dose or substitute different estrogen**
- **Evening primrose oil - 3 gram/day**
- **Danazol - 200 mg/day - days 14-28**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 91

Once breast cancer has been ruled out, communicating that no serious problem can be detected, that mastalgia is very common, and that it is usually self-limited will alleviate concern in most cases. In the remainder, avoiding methylxanthine intake may be helpful. Controlled studies of methylxanthine avoidance for relief of mastalgia are conflicting; avoidance does not alleviate nodularity nor reduce breast cancer incidence. Occasionally, substituting a more supportive brassiere, lowering the dose of estrogen, or substituting a different form of estrogen can be helpful. In women unrelieved by these measures, drug intervention can be useful. Cyclic pain is more responsive than non-cyclic pain. Three drugs have proven useful: Evening primrose oil, danazol, and bromocriptine. The latter two have side effects which have historically limited their use for extended periods. However, a recent randomized controlled trial of 200 mg of danazol on days 14-28 of the menstrual cycle for three cycles demonstrated clinical efficacy during all 3 months of drug administration with a drop-out rate of only 3%. An algorithm of breast pain management can be found in Appendix 3.

Sources:

1. Klimberg VS. Etiology and management of breast pain. In: Bland KI and Copeland EM (eds). *The Breast: Comprehensive Management of Benign and Malignant Disease*. Philadelphia, PA: W.B. Saunders Company, 1998, pp. 247-260.
2. O'Brien PMS, Abukhalil IEH. Randomized controlled trial of the management of premenstrual syndrome and premenstrual mastalgia using luteal phase-only danazol. *Am J Obstet Gynecol* 1999;180:18-23.

Signs & Symptoms of Breast Disorders:

Non-Palpable Mammographic Abnormalities

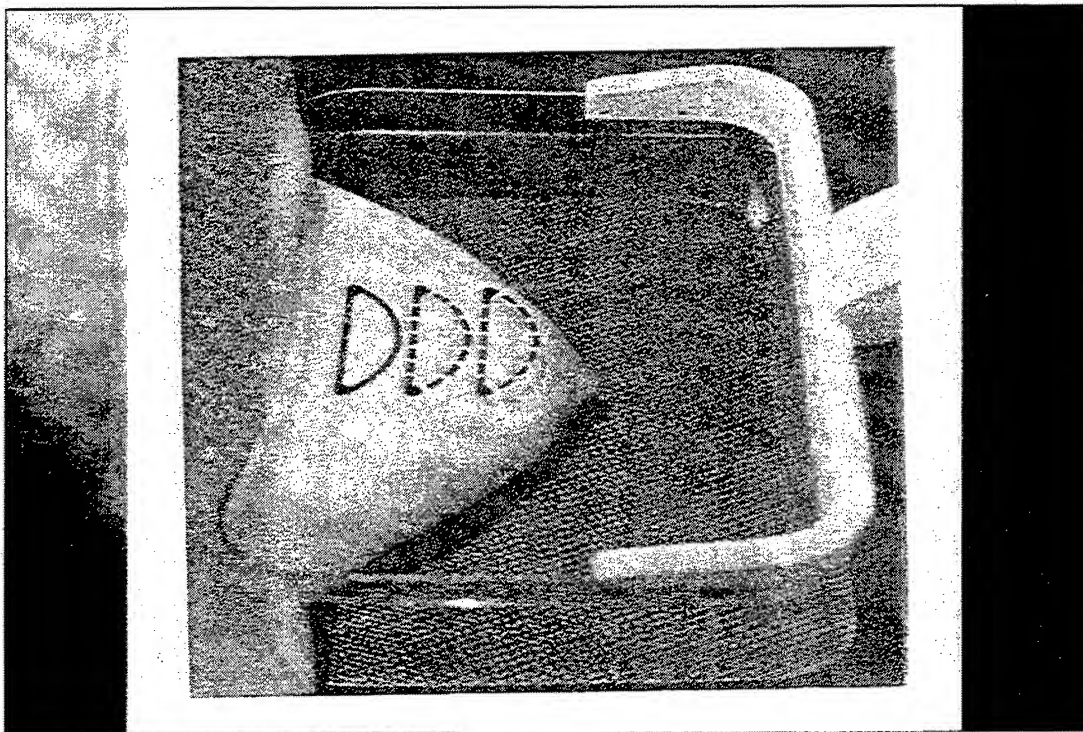
Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 92

Most screening mammograms will be interpreted as normal, but 5-10% will demonstrate a finding which requires further work up. Let's begin with a review of the techniques of mammography and what your patient experiences in the radiology department.

Source:

Bassett LW, Hendrick RE, Bassford TL et al. Quality Determinants of Mammography. Clinical Practice Guidelines No. 13. AHCPR Publication No. 95-0632. Rockville, MD. 1994, Agency for Health Care Policy and Research, US Department of Health and Human Services.



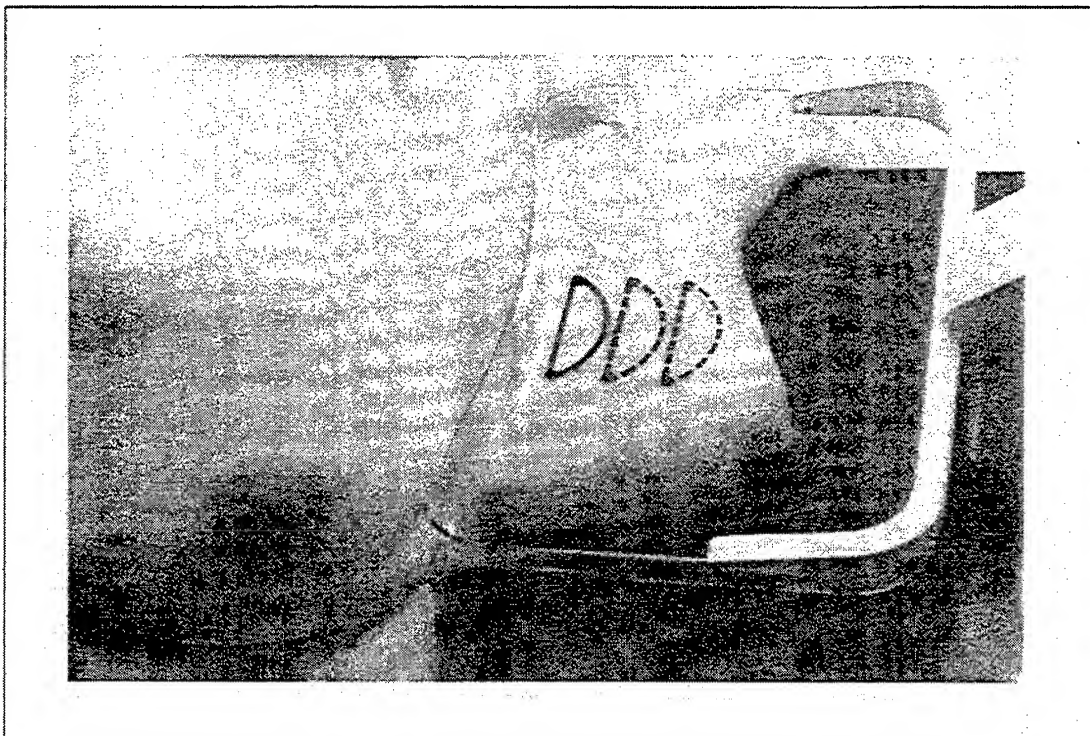
Slide Credit: from Svane G, Potchen EJ, Sierra A, and Azavedo E (Eds.). *Screening Mammography: Breast Cancer Diagnosis in Asymptomatic Women*. St. Louis: Mosby Publishers, 1993, p. 129. Used with permission.

SLIDE 93

The two standard views of a screening mammogram are the crandio-caudal (CC) and mediolateral oblique (MLO) views and these are usually performed in the standing position with the cassette parallel to the floor. This is an example of a CC, or head-to-toe view, with optimal breast compression. The CC view best demonstrates the subareolar, central, and medial portions of breast tissue.

Source:

Svane G, Potchen EJ, Sierra A, and Azavedo E (eds). *Screening Mammography: Breast Cancer Diagnosis in Asymptomatic Women*. St. Louis: Mosby Publishers, 1993.



Slide Credit: Svane G, Potchen EJ, Sierra A, and Azavedo E (Eds.). *Screening Mammography: Breast Cancer Diagnosis in Asymptomatic Women*. St. Louis: Mosby Publishers, 1993, p. 130. Used with permission.

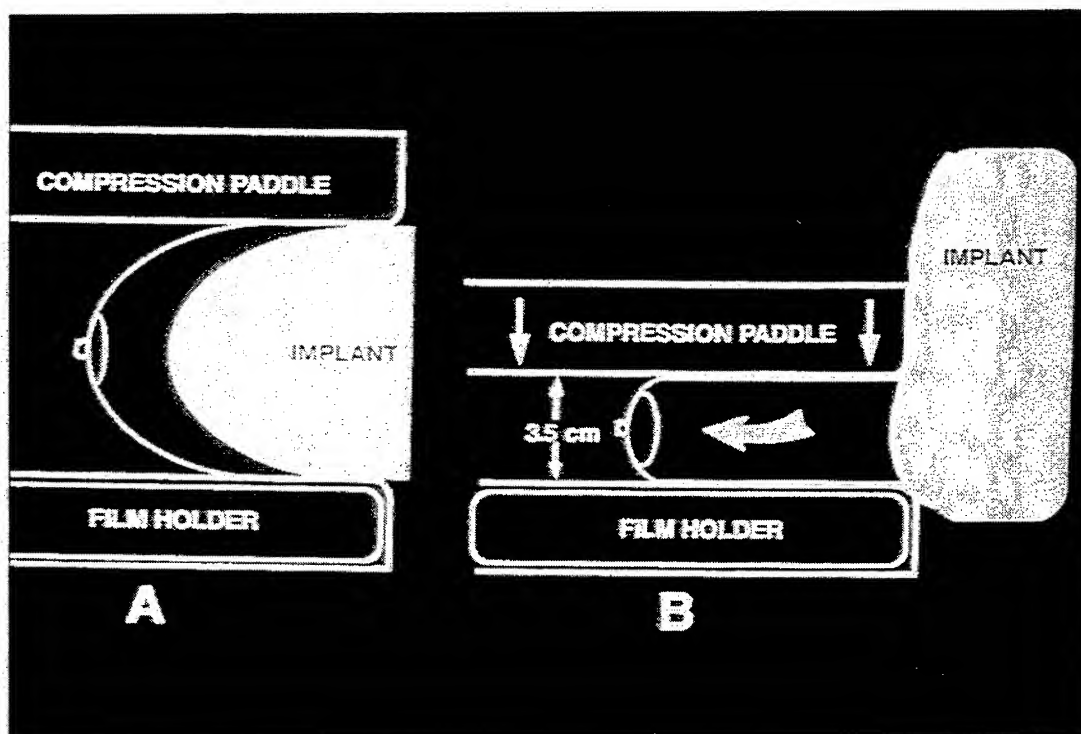
SLIDE 94

The MLO view images more of the breast than the CC view. In the MLO view the cassette is angled between 30 and 60 degrees. Adequate positioning includes visualization of the pectoralis major muscle to at least the nipple line, an open inframammary fold, and inclusion of the axillary tail of the breast.

Many patients complain about breast compression. Helping patients understand the purpose of the temporary discomfort of the test can increase compliance as well as patient satisfaction. The more the breast is compressed, the less radiation is required and the better the image produced. In addition, patients should be told that multiple films may be required to produce images that meet quality standards and that extra views do not necessarily imply that an abnormality has been found.

Source:

Svane G, Potchen EJ, Sierra A, and Azavedo E (eds). *Screening Mammography: Breast Cancer Diagnosis in Asymptomatic Women*. St. Louis: Mosby Publishers, 1993.



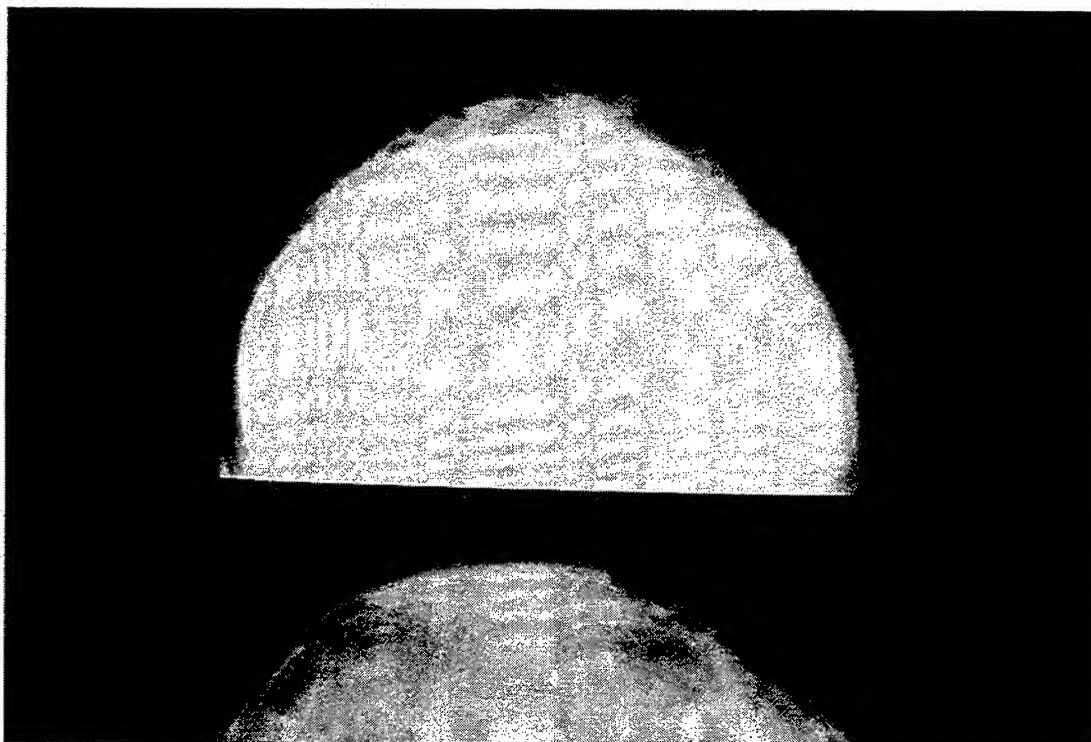
Slide Credit: From slide – lecture series, *Breast Imaging: A Guide for Clinicians*. Sandowsky NL, Feig SA, McLelland R. American College of Radiology, Reston VA. Slide No. 33. Used with permission.

SLIDE 95

Special consideration should be given to patients with breast implants, and technologists need proper training to perform a mammogram in these patients. This drawing illustrates the technique for positioning the breast in a woman with augmented breasts. Note that the implant is displaced behind the compression plates in illustration B on the right. This is called an Eklund view.

Sources:

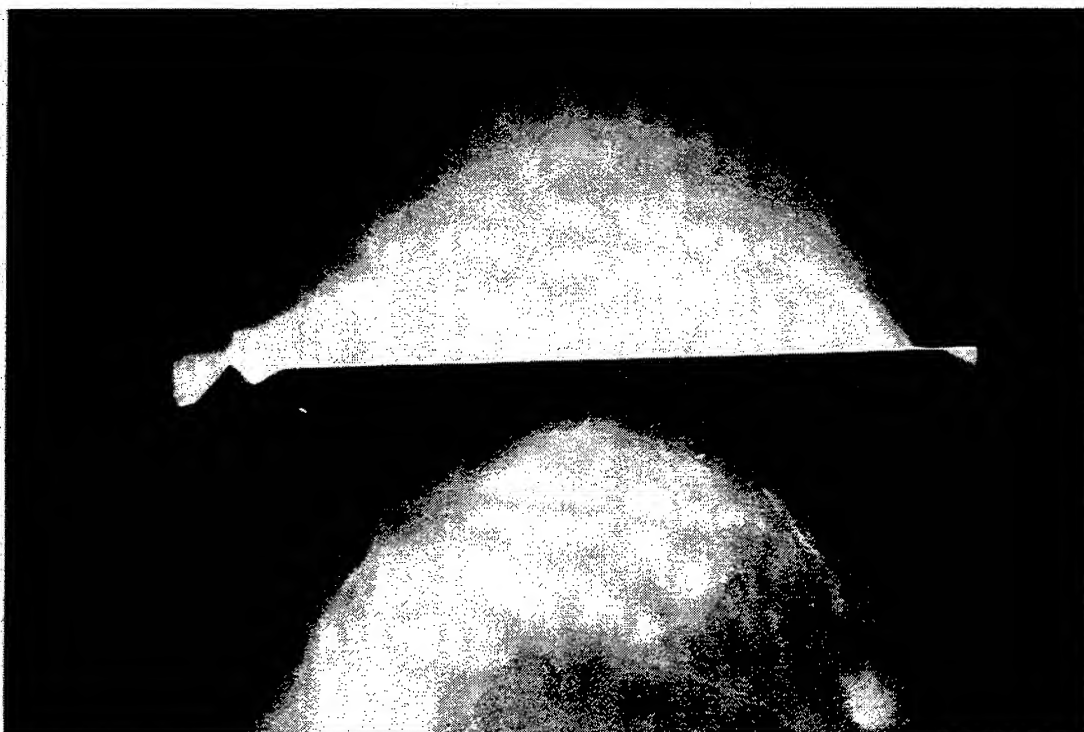
1. Slide - lecture series, *Breast Imaging : A Guide for Clinicians*. Sandowsky NL, Feig SA, McLelland R. American College of Radiology, Reston, VA.
2. Eklund GW. Improved imaging of the Augmented Breast. *AJR* 1988;151:469-473.



Slide Credit: From slide – lecture series, *Breast Imaging: A Guide for Clinicians*. Sandowsky NL, Feig SA, McLelland R. American College of Radiology, Reston VA. Slide No. 34. Used with permission.

SLIDE 96

The mammogram at the top of this slide shows the image produced when an implant is compressed in the typical manner. The implant is seen as an iso-dense area that comprises most of the film. A rim of breast tissue can be seen around the implant. By pushing the implant out of the way, a much better breast image is obtained, as shown in the lower portion of the slide, representing results produced with an Eklund view.



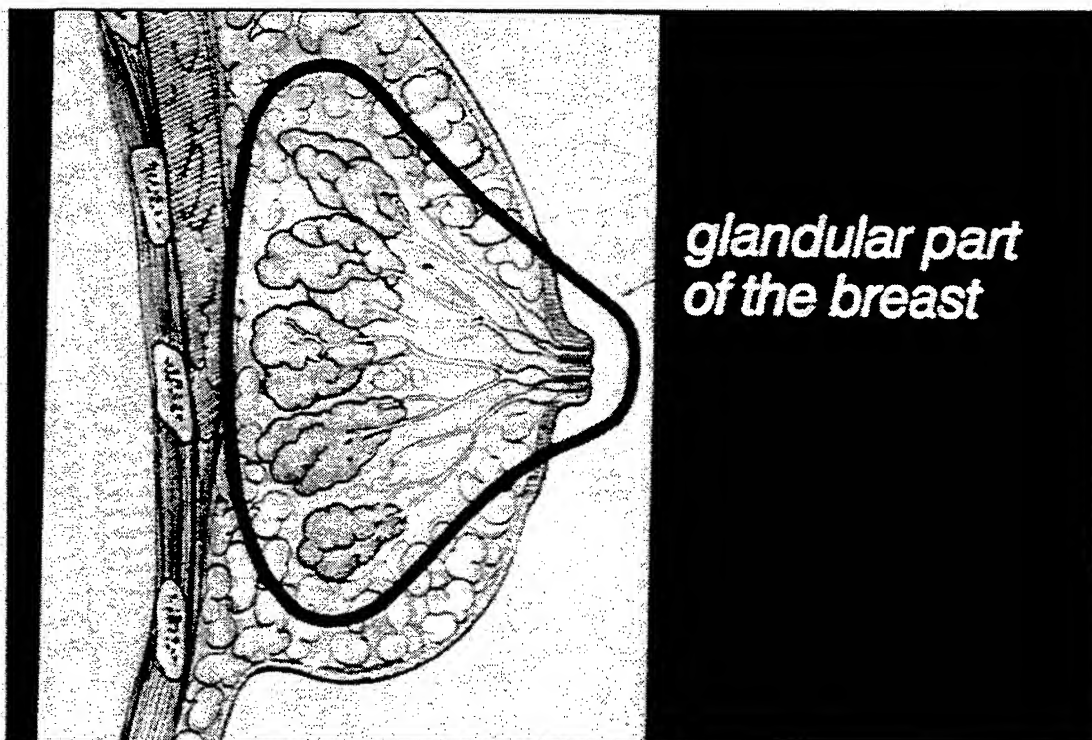
Slide Credit: From slide – lecture series, *Breast Imaging: A Guide for Clinicians*. Sandowsky NL, Feig SA, McLelland R. American College of Radiology, Reston VA. Slide No. 13. Used with permission.

SLIDE 97

- Mammogram interpretation is dependent on proper image quality. These images are of the same breast. The top image shows a breast that is not properly compressed. It could have mistakenly been read as a dense, glandular breast with no abnormality visualized. The image on the bottom shows the same breast with proper compression. It visualizes a small infiltrating cancer which would have been missed by the image on the top of the screen. An example such as this one can help patients understand the importance of adequate breast compression.

Source:

Mammography Quality Control Manual. Committee on Quality Assurance in Mammography. Reston, VA: American College of Radiology (ACR), 1990.



Slide Credit: National Cancer Institute, Bethesda, MD. Public Domain.

SLIDE 98

A mammogram images glandular tissue and fat differently and its interpretation depends on the contrast between the two. The anatomical features of the breast are life-cycle dependent and can influence the appearance of the mammogram. The parenchymal cells and ducts make up the glandular part of the breast, and will have a white appearance on the mammogram, whereas fat will appear dark or lucent. A radiologist's statement that the breasts are very glandular or dense indicates that there is little fatty tissue present in the breast; the mammogram will therefore be more difficult to interpret.

Source:

Bassett LW, Hendrick RE, Bassford TL et al. Quality Determinants of Mammography. Clinical Practice Guidelines No. 13. AHCPR Publication No. 95-0632. Rockville, MD. 1994. Agency for Health Care Policy and Research, US Department of Health and Human Services.



Slide Credit: From slide – lecture series, *Breast Imaging: A Guide for Clinicians*. Sandowsky NL, Feig SA, McLelland R. American College of Radiology, Reston VA. Slide No. 19. Used with permission.

SLIDE 99

When interpreting the mammogram, the radiologist will look for asymmetry in the appearance of white areas, indicating differences in the density of the tissues. The arrow here shows a density in the breast that is not matched on the opposite side, representing an infiltrating ductal carcinoma. It is possible to visualize it because it is located in a relatively fatty area of the breast. However, if this infiltrating ductal carcinoma were in the subareolar location of this breast, it would be impossible to visualize and detection of this cancer would be solely dependent on clinical breast examination.

Categories of Mammographic Readings

BI-RADS™ System

Category 1 - Normal mammogram

**Category 2 - Benign-appearing
abnormality**

**Category 3 - Probably benign/possibly
malignant, indeterminate**

Category 4 - Suspicious for malignancy

**Category 5 - Malignant until proven
otherwise**

Assessment Incomplete

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University. 2000.

SLIDE 100

Variability in interpretation of mammograms is a recognized problem. To address it, the American College of Radiology has developed the BI-RADS™ system of mammogram interpretation, which uses a standardized reporting format as follows:

Category 1--Negative, **Category 2**--Benign Finding, **Category 3**--Probably Benign Finding (indeterminate), **Category 4**--Suspicious Finding, and **Category 5**--Finding Highly Suggestive of Malignancy. Another category is termed assessment incomplete and additional diagnostic mammographic views or ultrasound are needed before a report is released by the radiologist.

Source:

American College of Radiology (ACR). *Breast Imaging Reporting and Data System (BI-RADS™)*. Second Edition. Reston, VA: American College of Radiology, 1995.

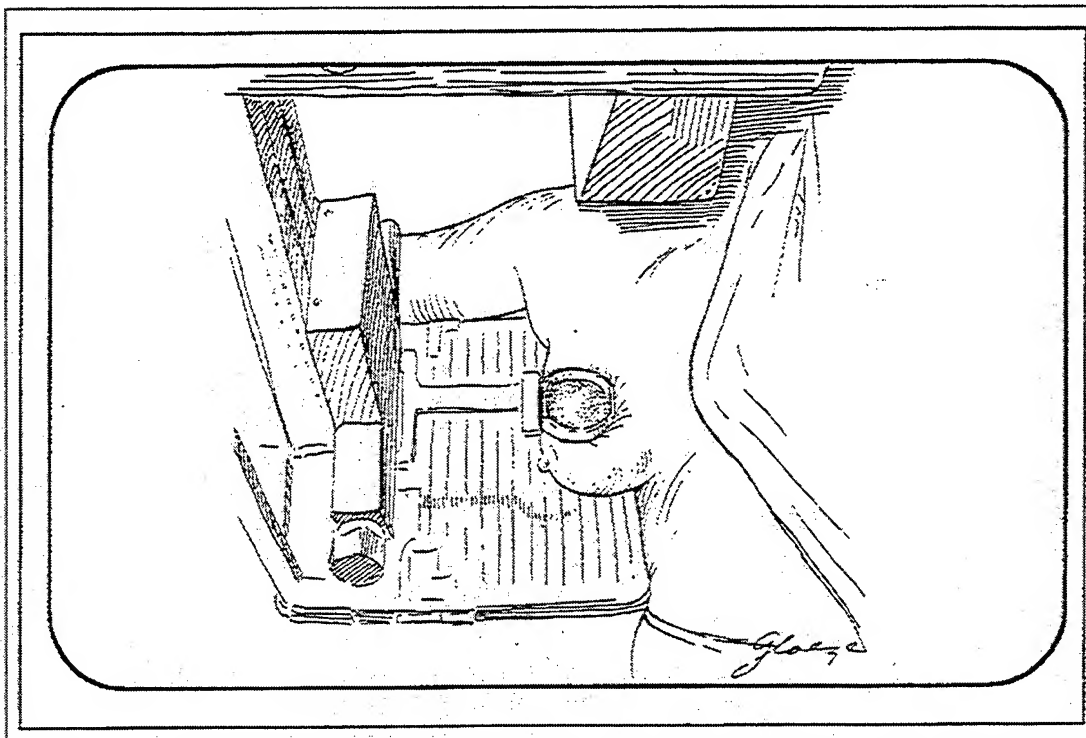
Common Mammographic DIAGNOSTIC Views

- 1. Cone compression**
- 2. Magnification**
- 3. Combination of these
two views**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 101

The most common diagnostic mammography views are (1) cone-compression (also called spot-compression), (2) magnification views, and (3) a combination of these two views.



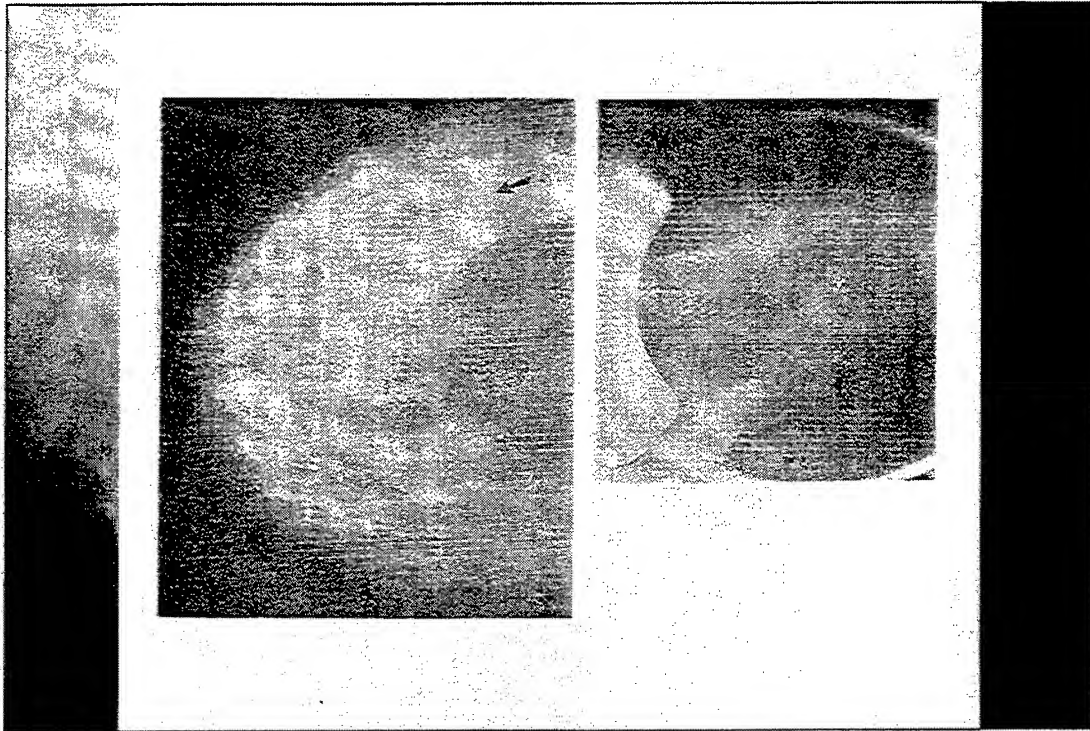
Slide Credit: From American College of Radiology, reference cited below, p. 105. Used with permission.

SLIDE 102

A cone compression view is performed using a device to selectively compress that portion of the breast in which the mammographic abnormality is imaged. This technique is used to evaluate densities; if a density persists after compression, its characteristics will be further defined, and if not, it will disappear. The disappearance of densities with cone compression can be explained by the overlapping of breast tissue that will naturally occur in some patients when a three-dimensional structure is imaged onto an X-ray film.

Source:

American College of Radiology (ACR). *Mammography Quality Control Manual*. Committee on Quality Assurance in Mammography. Reston, VA: American College of Radiology, 1990.



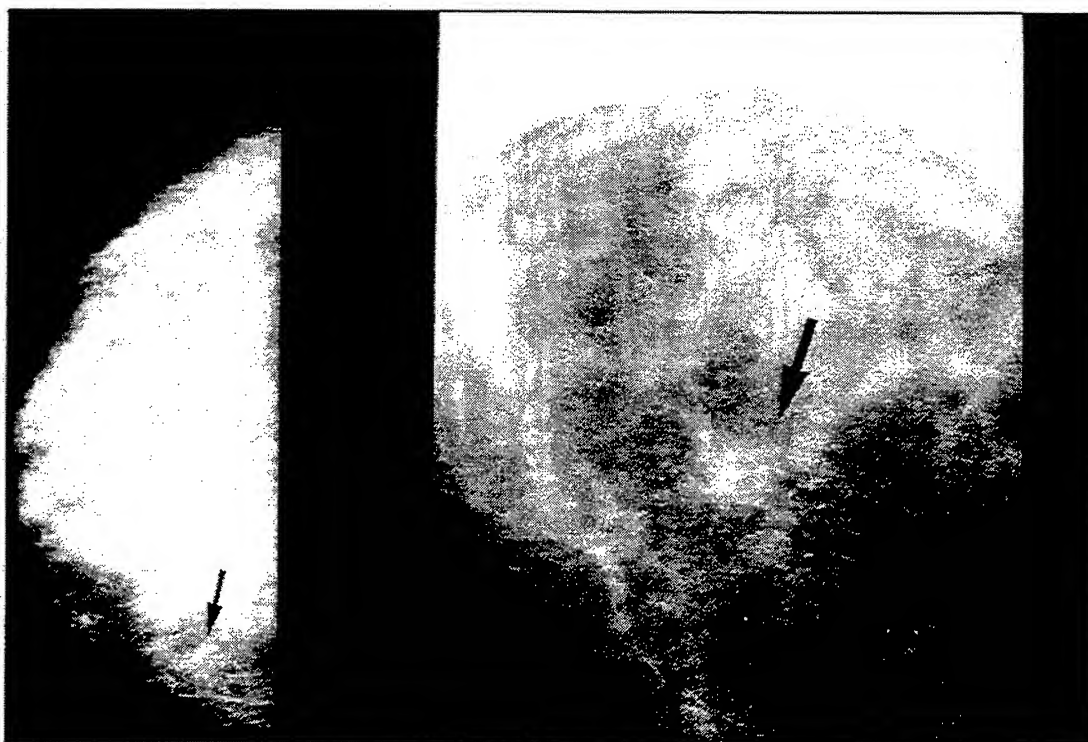
Slide Credit: From American College of Radiology, reference cited below, p. 105. Used with permission.

SLIDE 103

The mammogram on the left imaged a density in the breast, indicated by the black arrow. The film shown on the right illustrates the value of cone-compression, which demonstrated that the questionable abnormality simply represented a superimposition of normal tissue.

Source:

American College of Radiology (ACR). *Mammography Quality Control Manual*. Committee on Quality Assurance in Mammography. Reston, VA: American College of Radiology, 1990.



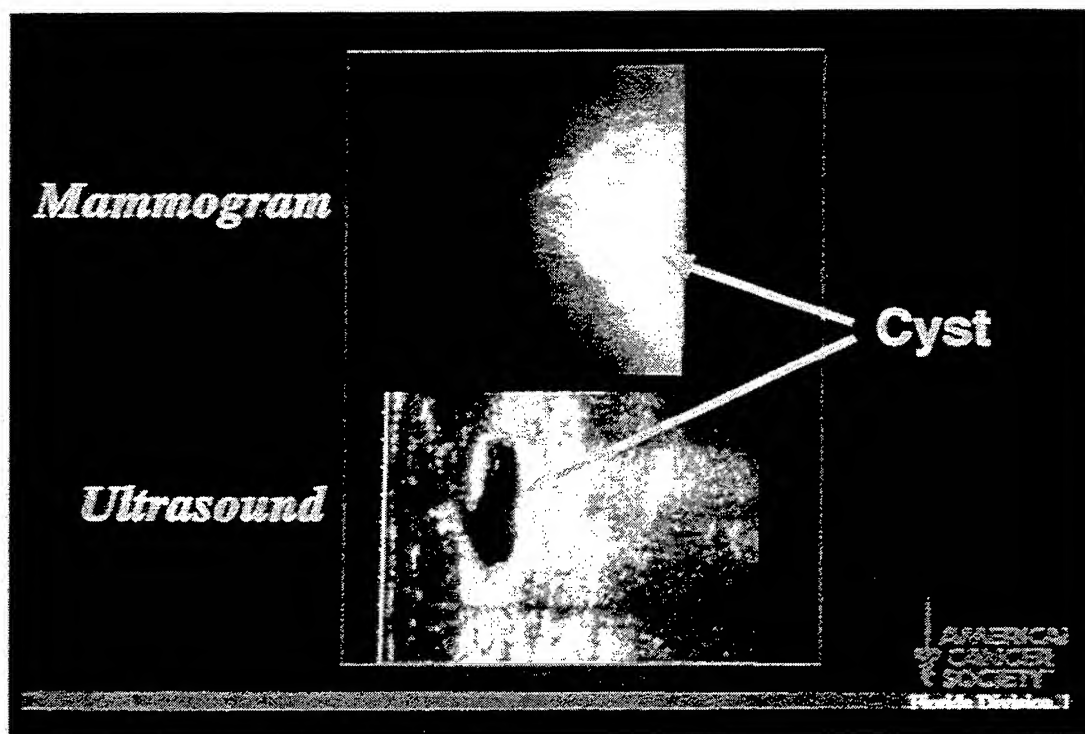
Slide Credit: From slide-lecture series, *Breast Imaging: A Guide for Clinicians*. Sandowsky NL, Feig SA, McLelland R. American College of Radiology, Reston, VA. Slide No. 29. Used with permission.

SLIDE 104

The diagnostic film shown on the right uses both magnification and spot-compression to more clearly demonstrate the abnormalities in the screening film on the left. The magnification component uses a special device which magnifies the calcifications, and demonstrates them to have a pleiomorphic character. The cone compression component demonstrates an irregular density which is even more suspicious than on the original film. This patient has a mammogram highly suspicious for cancer.

Source:

Mitchell R, Mitchell M, Nunnerty HB. Evaluation of magnification and paddle compression techniques in the assessment of mammographic screening detected abnormalities. *Clin Radiol* 1991;44:158-160.



Slide Credit: From Love, N. *Primary Care Considerations in Breast Diagnosis*. Slide-lecture program, slide No. 41. American Cancer Society, Florida Division, Tampa, FL, 1992. Used with permission.

SLIDE 105

Non-palpable mammographic smooth-walled densities can represent cysts or solid masses, and ultrasonography is used to distinguish the two. The top of this slide shows a smooth-walled density on a mammogram. This mass was not palpable on CBE. The corresponding ultrasound documents that the density is a cyst. This is apparent because of the dark interior which indicates fluid by ultrasound examination. To qualify as a simple cyst, a nodule must be void of internal echoes, or anechoic, have well-defined margins, and possess posterior acoustic enhancement. It is a dangerous practice to assume that a smooth-walled mammographic density is a cyst without proving it, as the differential diagnosis in the case of a solid mass includes carcinoma. If the mammographic abnormality is proven to be a simple cyst by ultrasound, no further intervention is needed, referral is unnecessary, and the woman can be reassured and placed into routine screening.

Source:

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.). *Textbook of Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.

Occult Mammographic Abnormalities

5-10% of screening mammograms need "call back" for diagnostic views

50-60% of diagnostic studies will resolve the initial problem

Currently, follow-up of radiologist recommendations is *suboptimal*

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 106

Most radiologists will indicate a need for further work-up when a mammogram is abnormal. Many unnecessary referrals to breast specialists can be avoided by following the recommendations of the radiologist and ordering the suggested diagnostic tests. Approximately 50-60% of initially abnormal screening mammograms will be placed into routine screening based on results of diagnostic views and ultrasound results. This approach is cost-effective and limits the fear and anxiety that is precipitated when patients are referred to a specialist.

On the opposite end of the follow-up spectrum, it has been repeatedly documented that there is inadequate follow-up of abnormal mammograms. Usually this is because women are not aware that the results are abnormal. In-office tracking systems are critical to good quality care and sound risk management.

Sources:

1. Bassett LW, Hendrick RE, Bassford TL et al. Quality Determinants of Mammography. Clinical Practice Guidelines No. 13. AHCPR Publication No. 95-0632. Rockville, MD. 1994. Agency for Health Care Policy and Research, US Department of Health and Human Services.
2. Mitchell R, Mitchell M, Nunnerty HB. Evaluation of magnification and paddle compression techniques in the assessment of mammographic screening detected abnormalities. *Clin Radiol* 1991;44:158-160.
3. Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.). *Textbook of Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.

Signs and Symptoms of *Breast Disorders*

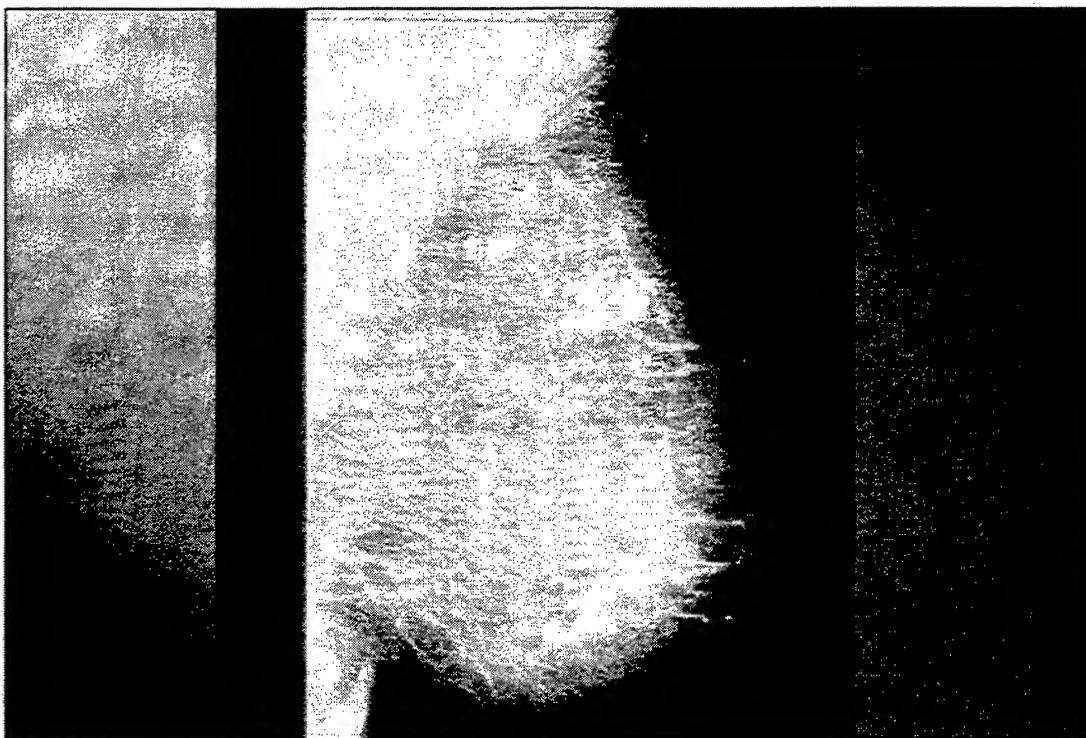
NON-PALPABLE MAMMOGRAPHIC ABNORMALITIES:

WORK-UP

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 107

The approach to a non-palpable mammographic abnormality depends in large part on the appearance of the abnormality and to the BI-RADS™ category into which it is placed.



Slide Credit: Tabar L, Dean P. *Teaching Atlas of Mammography*, 2nd Edition. New York, NY: Thieme Medical Publishers, Inc. 1983, plate 9A. Used with permission.

SLIDE 108

This is an example of an intramammary lymph node. Intramammary lymph nodes are easy to identify mammographically, because they have a lucent center. They need no further work up. This is an example of a category 2, benign mammogram. The patient should be reassured, and continued on a routine screening schedule.

Source:

Tabar L, Dean P. *Teaching Atlas of Mammography*, 2nd Edition. New York, NY: Thieme Medical Publishers, Inc., 1983.

Occult Mammographic Abnormalities

INITIAL WORK UP

1. Diagnostic mammogram

- Cone or spot compression
- Magnification

2. Ultrasound

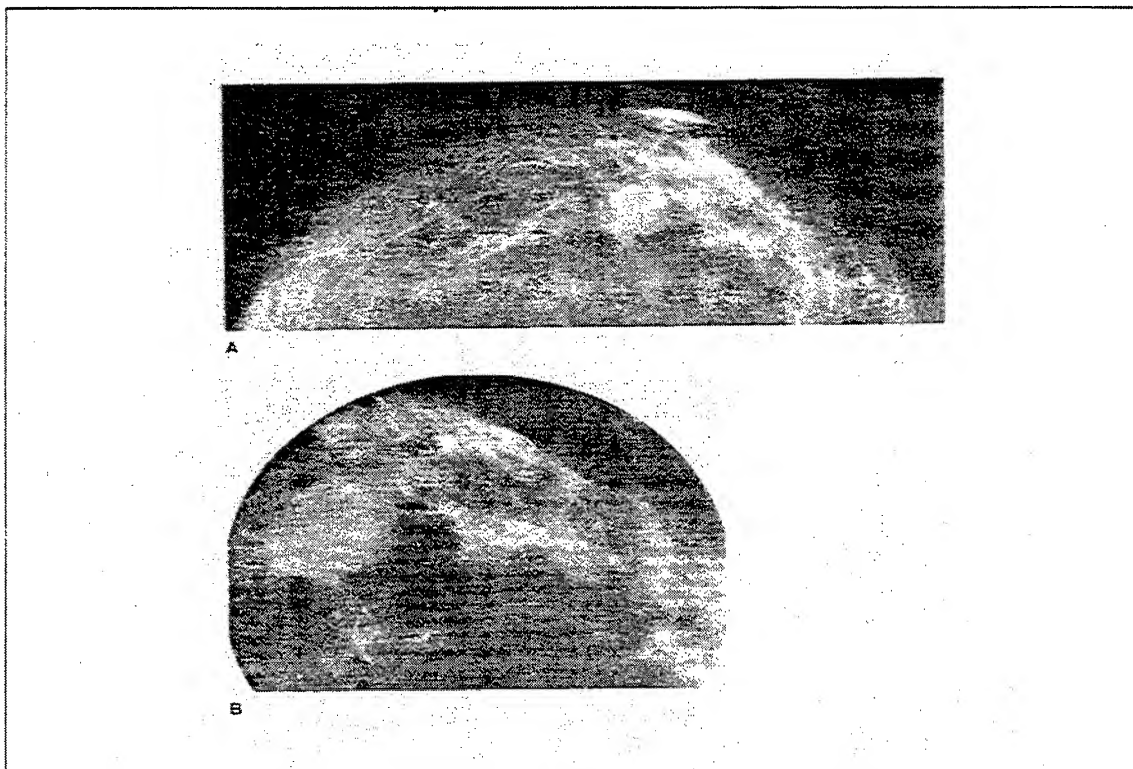
Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 109

When a mammogram is read as abnormal, a recommendation will usually be made for additional diagnostic views. At some facilities, these will be done at the same time as the screening views. At others, the patient will be called back. This call back is sometimes done by the radiology department, but usually the primary care physician is responsible for communicating the results of the mammogram and the need for further work up to the patient. As discussed previously, cone or spot compression is usually requested in order to delineate the edges of a density with more accuracy, magnification views are ordered to assess microcalcifications and small densities, and ultrasounds are ordered to differentiate cysts from solid masses.

Source:

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.). *Textbook of Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.



Slide Credit: Tabar L, Dean P. *Teaching Atlas of Mammography*, 2nd Edition. New York, NY: Thieme Medical Publishers, Inc, 1983, plate 51A and 51B. Used with permission.

SLIDE 110

This is another example of the application of diagnostic studies. The top film illustrates a smooth-walled mass on mammography. An ultrasound demonstrated the density to be solid. Although it appears smooth-walled on routine films, spot magnification delineates a poorly defined border. This finding warrants further work-up.

Source:

Tabar L, Dean P. *Teaching Atlas of Mammography*, 2nd Edition. New York, NY: Thieme Medical Publishers, Inc., 1983.

Occult Mammographic Abnormalities

Category 3 Mammogram - OPTIONS

- **Interval mammography**
- **Image-guided biopsy**
- **Surgical removal**

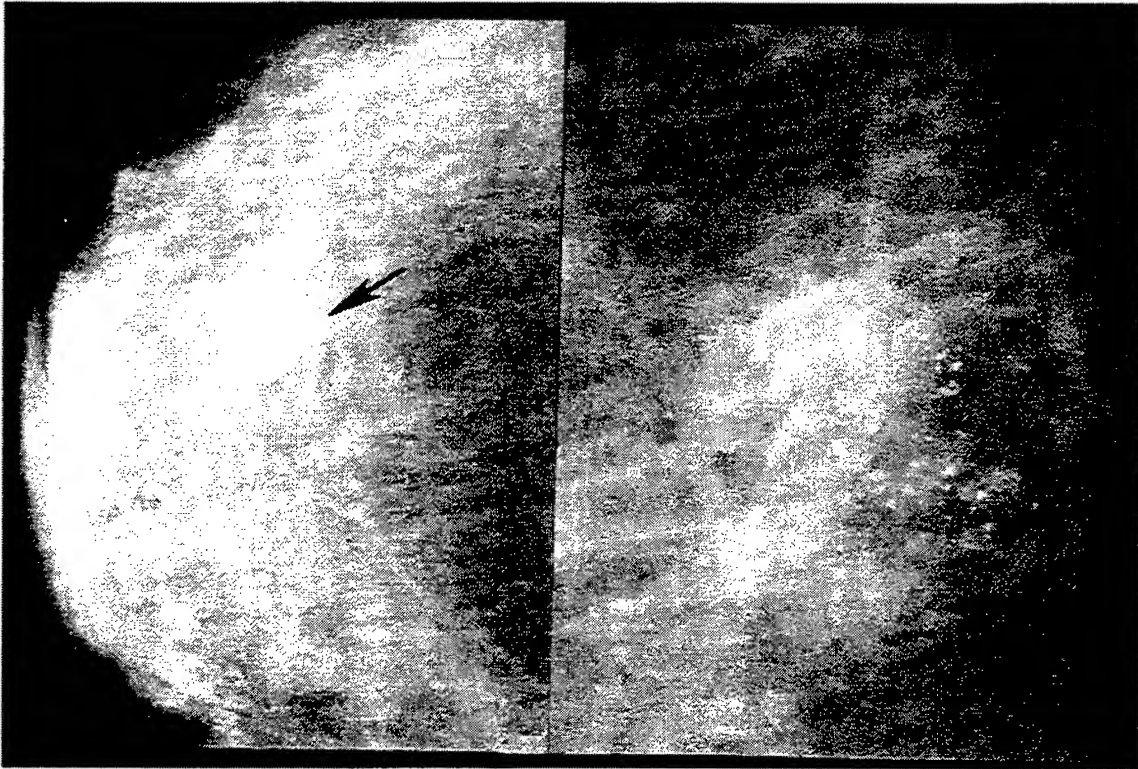
Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 111

Category 3 mammograms include indeterminate findings which could represent malignancy but are most often benign. Depending on the preferences of the patient, her risk factors and her hormonal status, options for a woman with a category 3 mammogram include 6-month follow-up of the lesion for 1 year with yearly follow-up for two more, image-guided biopsy, or surgical removal. The interventional techniques will be discussed at the end of this section. The patient chose surgical removal of the lesion demonstrated in the last slide and it proved to be a fibroadenoma.

Sources:

1. McCombs MM, Bassett LW, DeBruhl N, et al. Imaging-guided needle biopsy of the breast. In: Bassett LW, Jackson V, Gahan R, et al (Eds.). *Diagnosis of Diseases of the Breast*. Philadelphia, PA: W.B.Saunders, 1997.
2. Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.). *Textbook of Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.



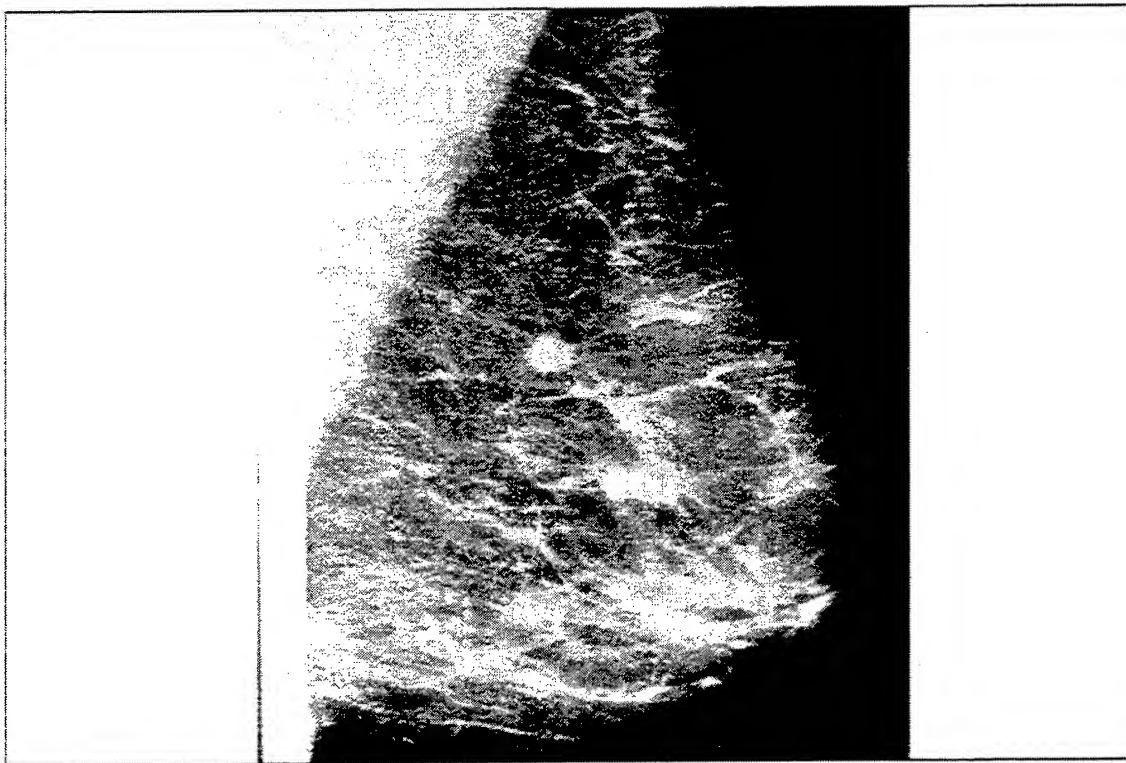
Slide Credit: From slide – lecture series, *Breast Imaging: A Guide for Clinicians*. Sandowsky NL, Fieg SA, McLelland R. American College of Radiology, Reston, VA, Slide No. 23. Used with permission.

SLIDE 112

The arrow on the left side of this slide demonstrates the presence of microcalcifications which appear suspicious for malignancy. Magnification views demonstrate the pleiomorphic nature of these calcifications, raising the index of suspicion. Rather than being suspicious, most mammographic calcifications are associated with benign processes (80% of the time), and it is helpful for patients to understand this. Terms used to describe benign-appearing calcifications include scattered, punctate, milk-of-calcium, or lobular,” among others. Malignant descriptors include terms such as “clustered, pleiomorphic, granular, or casting,” among others. This mammogram is classified at least as a category 4. To be most cost-effective, the abnormality should be removed surgically rather than undergo radiologic intervention, as the chances of malignancy are extremely high and one procedure will potentially be both diagnostic and therapeutic.

Sources:

1. Tabar L, Dean P. *Teaching Atlas of Mammography, 2nd Edition*. New York, NY: Thieme Medical Publishers, Inc., 1985.
2. Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.). *Textbook of Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998. pp. 295-313.



Slide Credit: Tabar L, Dean P. *Teaching Atlas of Mammography*. 2nd Edition. New York, NY: Thieme Medical Publishers, Inc, 1985, plate 59A. Used with permission.

SLIDE 113

The density in the upper portion of this film is an example of a mass with irregular borders and, in this case they are spiculated. This is highly suggestive of carcinoma, and a surgical excision will be necessary.

Source:

Tabar L, Dean P. *Teaching Atlas of Mammography*. 2nd Edition. New York, NY: Thieme Medical Publishers, Inc., 1985.

Occult Mammographic Abnormalities--Work-up

Interventional Procedures

- **Image-guided biopsy**
 - **Ultrasound**
 - **Stereotaxic**
- **Surgical excision**
 - **Needle localization/biopsy**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

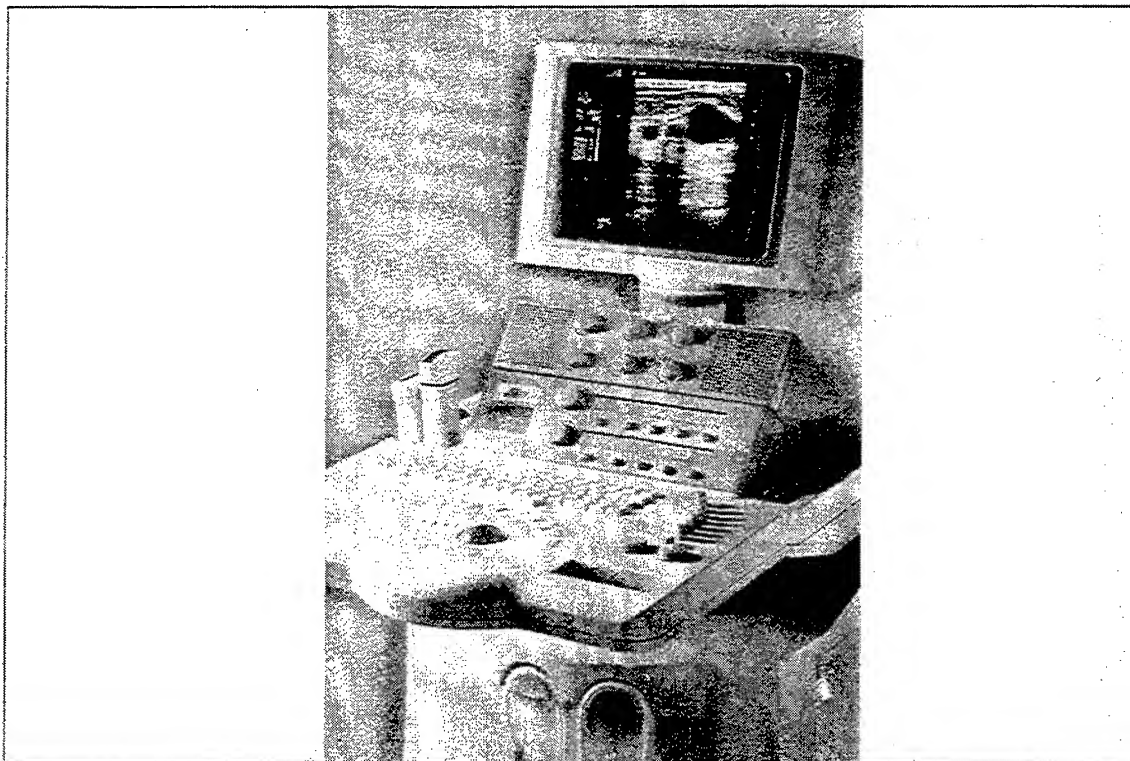
SLIDE 114

Mammograms read as category 3 (probably benign or indeterminate) can be managed by the primary care clinician or by referral, depending on the preferences and anxiety level of the woman and the confidence of the clinician in her/his own skills as well as those of the interpreting radiologist.

As indicated earlier, if a mammogram is read as indeterminate (category 3) a patient has three options: interval mammography with intervention if there are changes, image-guided biopsy, or surgical excision. This section briefly explains the techniques used in interventional procedures from the patient's perspective. There are three types of interventional procedures: Image-guided biopsy under either ultrasound, or stereotaxic guidance, or surgical excision using needle localization/biopsy.

Sources:

1. McCombs MM, Bassett LW, DeBruhl N, et al. Imaging-guided needle biopsy of the breast. In: Bassett LW, Jackson V, Gahan R, et al (Eds.), *Diagnosis of Diseases of the Breast*. Philadelphia, PA: W.B.Saunders, 1997.
2. Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.). *Textbook of Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.



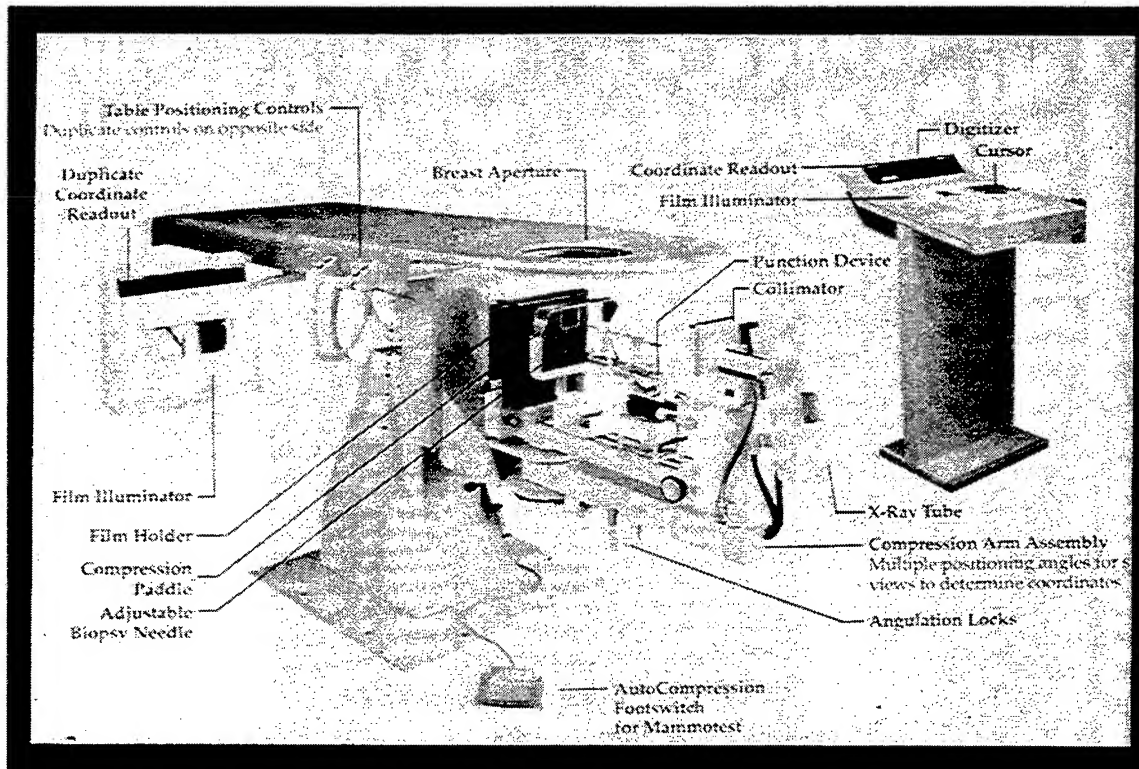
Slide Credit: Acoustic Imaging Technologies Corporation brochure, Phoenix, AZ, 1996. Used with permission.

SLIDE 115

When an interventional procedure is done under ultrasound guidance, the patient is placed in the supine position. The procedure is relatively comfortable, although the equipment for it is visible to the patient, which can be troubling for some.

Source:

Acoustic Imaging Technologies Corporation Brochure, Phoenix AZ, 1996.



Slide Credit: Fisher Imaging brochure, Denver, CO. Used with permission.

SLIDE 116

When an interventional procedure is done under stereotaxic guidance, the patient lies prone for the procedure, with her head turned to the side. This position may be difficult to sustain for frail women or those with shoulder or neck arthritis, as the procedure takes approximately 45 minutes. Women over 300 pounds are not candidates because the table for the procedure will not accommodate the weight of the patient. All of the equipment is located under the table, out of the patient's view. The procedure requires breast compression which can make it uncomfortable for some patients. An alternative stereotaxic device attaches to a standard mammogram machine and the patient sits during the procedure, but its use is not common.

Source:

Kopans DB (Ed.) *Breast Imaging*. Philadelphia, PA: Lippincott-Ravin, 1997.

**Occult Mammographic
Abnormalities--Work-up**
Interventional Procedures

IMAGE-GUIDED BIOPSY

- Fine needle aspiration
- Core biopsy
- Mammotome

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University. 2000.

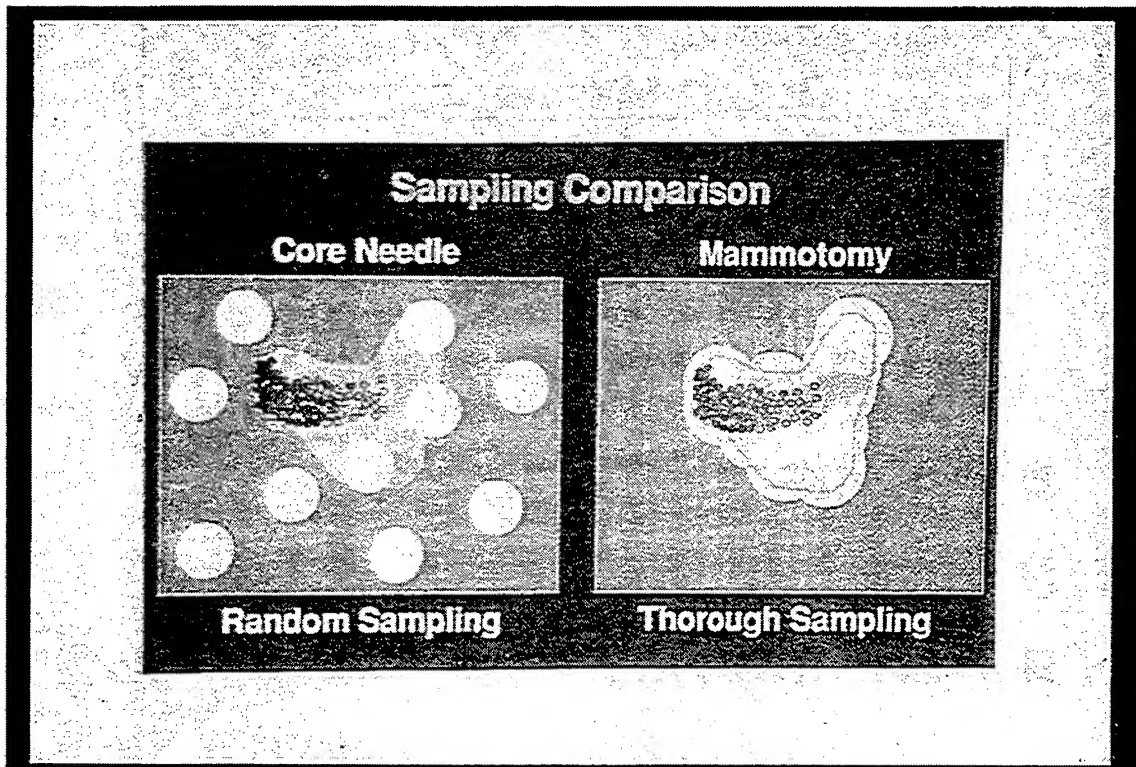
SLIDE 117

There are three biopsy methods that can be performed under image guidance, whether using ultrasound or stereotaxic techniques. The radiologist will select the most appropriate for each patient and lesion. Fine-needle aspiration uses a 21-23 gauge needle and samples tissue cytologically. Core biopsy and mammotome procedures sample tissue histologically.

Image-guided biopsies provide a more definitive answer than interval mammography while avoiding surgical intervention.

Source:

Kopans DB (Ed.) *Breast Imaging*. Philadelphia, PA: Lippincott-Ravin, 1997.



Slide Credit: Mammotomy technique may reduce biopsy sampling errors. *Oncology News* 1997;6:7. Used with permission.

SLIDE 118

Core needle biopsies are done with 14 to 18-gauge devices that take a random sampling of tissue. A mammotomy removes all of the radiologic abnormality through a series of sequential core biopsies aided with a suction device. Another technique called ABBI uses a 1-2 cm large coring device to remove an abnormality. This can only be done under stereotaxic guidance. Neither the ABBI or mammotome techniques are widely available in 1999, but they are becoming more common. Many protocols for image-guided biopsies require interval follow-up to ensure mammographic stability of the lesion. The false-negative rate is yet to be firmly established, but early indications are that it is quite low.

Sometimes a woman desires a definitive answer regarding an indeterminate mammographic lesion, and in this case, needle localization/biopsy will be recommended.

Sources:

1. Parker SE, Jobe WE (Eds.). *Percutaneous Breast Biopsy*. New York, NY: Raven Press. 1993.
2. *Oncology News*, "Mammotomy Technique May Reduce Biopsy Sampling Errors." 1997, 6:3, 7.
3. Meyer JE: Value of large-core biopsy of occult breast lesions. *AJR* 1992;158:991-992

Occult Mammographic Abnormalities
NEEDLE LOCALIZATION

- **Mammographic Guidance**
- **Ultrasound Guidance**
- **Stereotaxic Guidance**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University. 2000.

SLIDE 119

When surgical excision of an occult mammographic abnormality is preferred for category 3 mammograms or recommended for category 4 or 5 mammograms, the radiologist will perform a needle localization prior to the procedure. This can be done using any of the three imaging techniques already discussed.

Although routine mammographic guidance is usually preferred, it is important to know that the procedure depends on the skill of a radiologist to estimate the location of an occult abnormality using two mammographic images, the craniocaudal and straight medial-lateral view. Note that the latter view is different from the mediolateral-oblique view done during screening mammography. If the lesion is not visible on both views, mammographic needle localization is difficult and usually impossible.

Cancellation of a surgical procedure due to inability to localize the abnormality in both views can be extremely distressing to patients and their families. The most comforting discussion that a patient can have under these circumstances is an explanation of why the event occurred, the current impression of the mammographic abnormality, and a plan of action for further work up.

Source:

Hermann G, Schwartz I, Tartter PI (Eds.). Nonpalpable breast cancer: Diagnosis and management. New York, NY: Igaku-Shoin, 1992

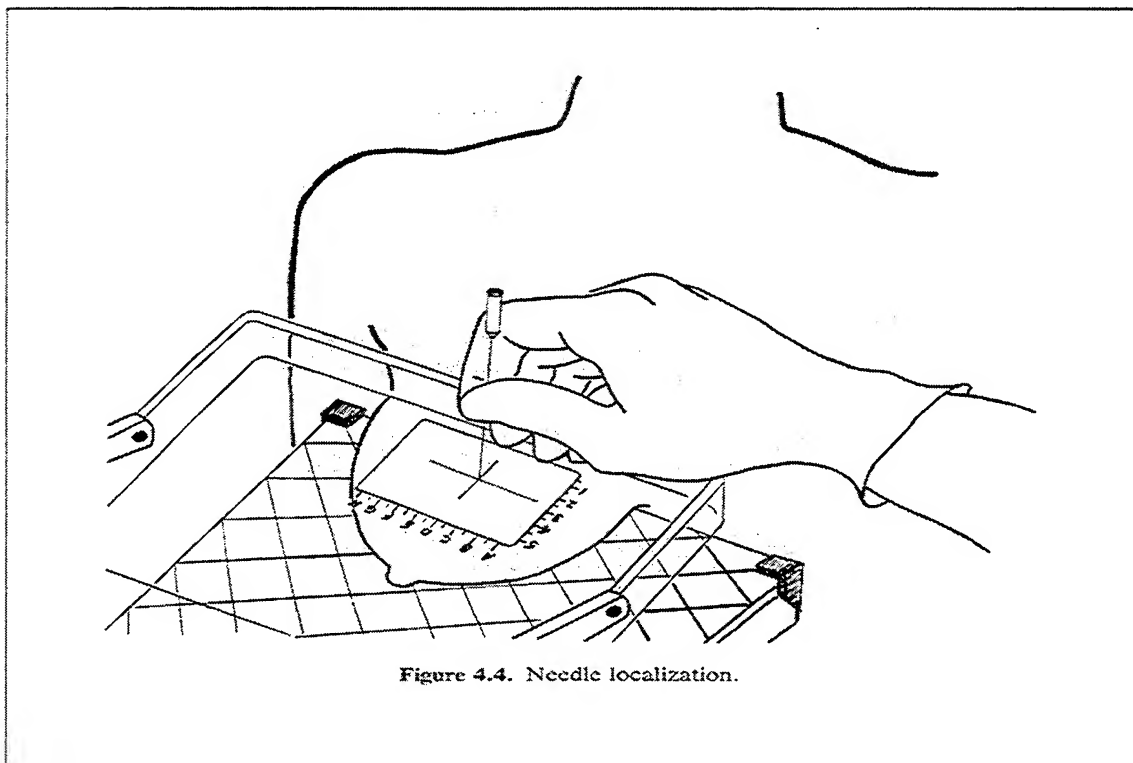


Figure 4.4. Needle localization.

Slide Credit: from Hermann G. Schwartz I, Tartter PI (Eds.). *Nonpalpable breast cancer: Diagnosis and management*, Chapter 4, figure 4-4. New York, NY: Igaku-Shoin, 1992. Used with permission.

SLIDE 120

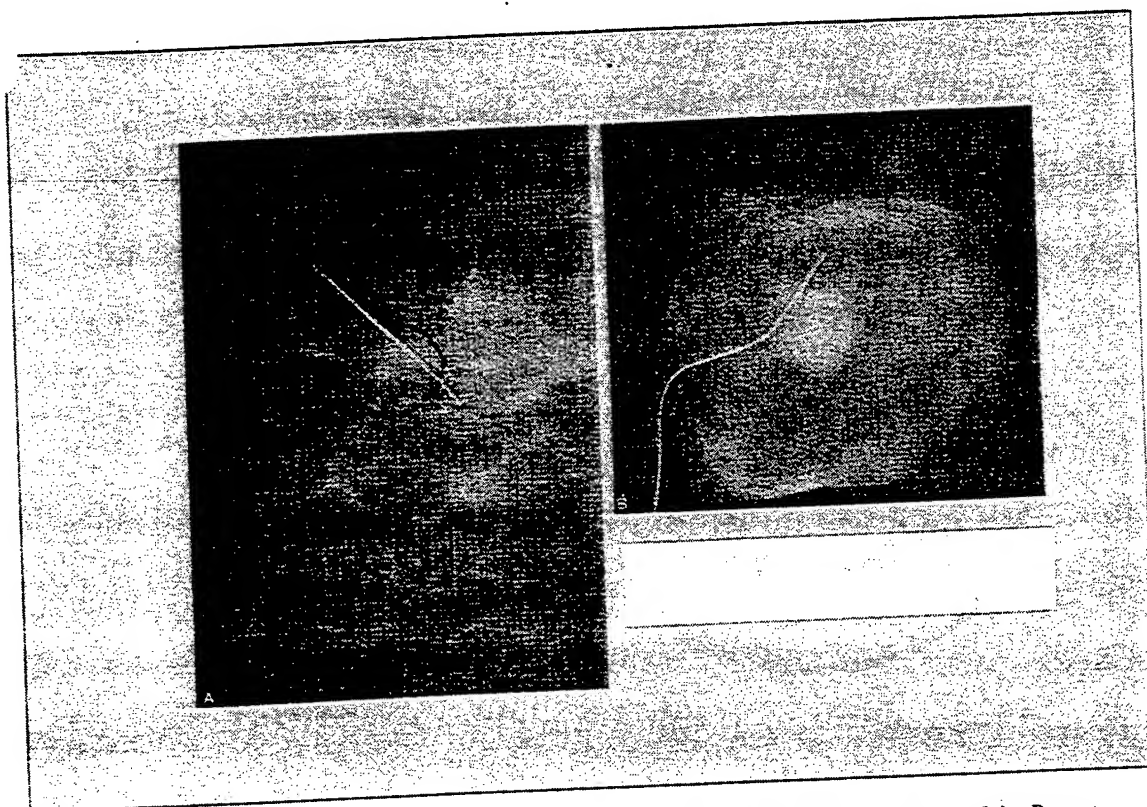
It is important for the referring provider to know that a patient is required to be in the sitting position during the needle localization procedure using standard mammography. Administration of sedatives prior to the procedure is contraindicated because of hypotension and loss of consciousness when upright. Despite this, most women tolerate the procedure well.

Alternative methods of localization include use of stereotaxic mammography, ultrasonography, or CT scan, all of which are usually capable of imaging an abnormality in a single view. It is important to know, however, that ultrasound is not capable of imaging calcifications and some other mammographic abnormalities, and lesions cannot be imaged using CT scan or stereotaxic techniques with 100% assurance. In these rare cases, interval mammography will be recommended.

Sources:

Hermann G. Schwartz I, Tartter PI (Eds.). *Nonpalpable breast cancer: Diagnosis and management*. New York, NY: Igaku-Shoin, 1992

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.). *Textbook of Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.



Slide Credit: Donegan WL. Diagnosis. In: Donegan WL and Spratt JS (Eds.) *Cancer of the Breast*. Chapter 10, figure 10-54. Philadelphia, PA: W.B. Saunders, 1995. Used with permission.

SLIDE 121

If needle localization can be accomplished, a needle will be directed towards the estimated location of the abnormality, an image obtained, and the needle redirected until it is as close to the abnormality as possible. A wire will then replace the needle and the surgeon will remove the abnormality using the wire as a guide. It is critical that the surgeon document successful removal of the abnormality by obtaining an intraoperative mammogram of the specimen (specimen mammogram), as shown on the right in the above slide. If unsuccessful, a second specimen is usually obtained and if that is unsuccessful, the needle localization/biopsy is repeated when the patient can tolerate it, usually in 2-3 weeks.

Sources:

1. Hermann G, Schwartz I, Tartert PI (Eds.). Nonpalpable breast cancer: Diagnosis and management. New York, NY: Igaku-Shoin, 1992
2. Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.). *Textbook of Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998. pp. 295-313.

Occult Mammographic Abnormalities: Work-up



**No News
is
No News**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 122

To conclude this section on work-up of occult mammographic abnormalities, a discussion of communication and follow-up is important. Many studies have documented that tracking and follow-up of abnormal screening mammograms is not optimal. It is the responsibility of the clinician ordering the mammogram to be sure that the results are obtained and that follow-up of abnormalities is done in a timely fashion. It is very helpful to have the patient involved in the follow-up loop. A "no-news-is-good-news" policy for reporting results is not an optimal policy and a tracking system with clear communication of results to all patients should be considered as a sound alternative from both risk management and patient care perspectives. Do not depend on the receipt of reports as your only method of tracking. It is possible for reports to be delayed, filed inappropriately, or never received at all. An algorithm summarizing the work up of a non-palpable mammographic abnormality can be found in Appendix 4.

Sources:

1. Bassett LW, Henrick RE, Bassford TL, et al. *High-Quality Mammography: Information for Referring Providers*. Quick Reference Guide for Clinicians No. 13. Rockville, MD: Agency for Health Care Policy and Research. Public Health Service, U.S. Department of Health and Human Services, 1994. AHCPR Publication No. 95-0633
2. Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health 1998; Vol. 3, No. 5. <http://www.Medscape.com>. (Appendix 10).

Signs and Symptoms of Breast Disorders: Breast Mass or Asymmetrical Thickening

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 123

Breast cancer presents as a palpable mass in the majority of cases, despite the widespread use of screening mammography. The prevalence of benign breast masses compared to those of malignant origin is at least 4:1. Distinguishing between benign disease and malignancy can be challenging, and demands balance between the goals of high quality, cost-effective care that maximizes the timely diagnosis of malignancy, while avoiding unnecessary surgical biopsy.

Source:

Rimer B. *Breast Cancer Screening*. Philadelphia, PA: Lippincott-Raven, 1996.

Breast Mass/Asymmetry

Physician's Insurers Association of America 1995:

Most Common Reason for:

Malpractice litigation : *Breast Cancer*

Claims Paid : *Breast Cancer*

**Successful claim : *Failure to be
impressed with
clinical findings***

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 124

In a 1995 study by the Physician's Insurers Association of America, the most common reason for malpractice litigation was breast cancer. Breast cancer claims also accounted for the highest amount of claim dollars paid. The most common error made by physicians in these cases was to discount either the patient's or their own findings of a palpable abnormality on CBE.

Source:

Physician Insurers Association of America. *Breast Cancer Study*. Lawrenceville, NJ: Physician Insurers Association of American, 1995.

Breast Mass/Asymmetry

	<u>Median Tumor Size</u>
Routine CBE	- 28mm
Experienced examiners	- 16mm
Screening mammography*	- 13mm
Physical palpation threshold	- 6mm

****Goal of screening mammography - >50%
Stage 0 or I (2 cm or less in size)***

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 125

In the 1940s, when BSE was first advocated, the majority of breast cancer presented in locally advanced stages. The breast exam was not considered part of the routine physical exam, and the tumor size at diagnosis was usually greater than 5 cm. As mammography screening trials began in the 1970s, we began to ask ourselves whether we could palpate what the x-ray demonstrated. This feedback allowed our skills to improve. Currently, the mean size of palpable breast cancer is 28 mm, and of mammographically detected cancer, 13 mm. The threshold for detection of palpable tumors is much lower, estimated to be about 6 mm, and about 3 mm for some mammographic tumors. Most breast cancers examined by those with experience are palpable by about 16 mm in size. The goal of the session this afternoon will be to teach the skills of palpation of tumors 1 cm or less in size. This section of the workshop will focus on work up of detected palpable abnormalities.

Sources:

1. Reintgen D, Berman C, Cox C, et al. The anatomy of missed breast cancers. *Surg Oncol* 1993;2:65-75.
2. Bassett LW, Liu T-H, Giuliano AE, et al. The prevalence of carcinoma in palpable vs impalpable mammographically detected lesions. *AJR Am J Roentgenol* 1991;157:21-24.

Breast Mass/Asymmetry

■ **Normal CBE = Absence of mass thickening asymmetry**

Any asymmetrical mass, even if only a two-dimensional thickening, represents an abnormal finding on CBE

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 126

The detection and diagnosis of breast masses is far more challenging than in the past, and can be subtle. The definition of a normal clinical breast exam is one of exclusion - the absence of an abnormality.

Although it is correct that breast cancer usually presents as a three-dimensional firm, non-tender mass, exceptions to this statement make reliance on it to distinguish cancer from benign disease very hazardous. Any asymmetrical mass, even if only a two-dimensional thickening, demands further attention.

Source:

Osuch JR. Abnormalities on physical examination. In Harris JR, Lippman ME, Morrow M, et al., (Eds.), *Diseases of the Breast*. Philadelphia, PA: Lippincott-Raven Publishers, 1996, pp. 110-114.

Breast Mass/Asymmetry Diagnostic Mammography

2 GOALS:

- *Characterization of the CBE finding (if visible)*
- *Detection of Occult Abnormalities*



Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 127

Up until this point, we have discussed mammography in asymptomatic women. Its application in symptomatic disease is much different and this understanding is critical in making a timely diagnosis of breast cancer.

Mammography in a women with a breast mass is done for two reasons:

- (1) to characterize the abnormal CBE finding (if it is visible mammographically), and (2)
- to rule out clinically occult lesions in the non-involved breast tissue. **Diagnostic mammography is NOT used to rule out breast cancer in the palpable abnormality, and this point cannot be overemphasized.**

Source:

Osuch JR. Abnormalities on physical examination. In Harris JR, Lippman ME, Morrow M, et al., (Eds.), *Diseases of the Breast*. Philadelphia, PA: Lippincott-Raven Publishers, 1996, pp. 110-114.

Breast Mass/Asymmetry

PIAA 1995 - Women who Bring Suit for Failure to Diagnose Breast Cancer

- ***60% of cases presented as patient - discovered masses***
- ***63% - 68% are premenopausal***
- **Breast cancer incidence:**
 - ***75% of patients are postmenopausal***

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 128

In the 1995 PIAA study, 60% of the women with breast cancer presented with a self-discovered mass. Although most women who present with breast masses who have breast cancer are post-menopausal, the majority who sue for failure to diagnose breast cancer are premenopausal.

Sources:

1. Osuch JR, Bonham VL. The timely diagnosis of breast cancer. *Cancer* 1994;74:271-278.
2. Physician Insurers Association of America. *Breast Cancer Study*. Lawrenceville, NJ: Physician Insurers Association of American, 1995.

Breast Mass/Asymmetry False Negative Mammography	
Breast Cancer Detection & Demonstration Project	
AGE	Rate of False-Negative Mammography
40	36%
70	9%
Physician Insurance Association of America 1995	
Mammogram Results	Frequency
Normal	49%
Equivocal	19%
Abnormal	32%

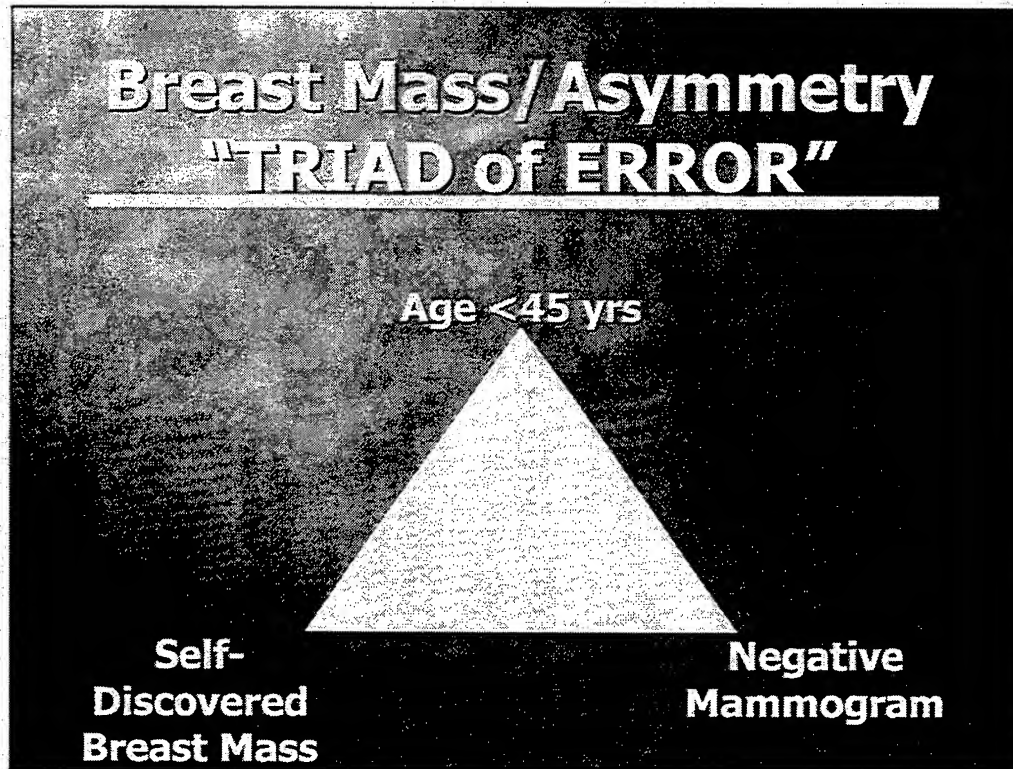
Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 129

Although mammograms can be read as normal in women with breast masses because of technical or reading errors, obscuring of the lesion by dense normal tissue is the most common reason for a false-negative mammogram. Dense tissue is more common in young women but can occur in any age group. In the Breast Cancer Detection and Demonstration Project in the late 1970s and 1980s, 36% of women aged 40 with breast cancer had a normal mammogram, compared with 9% of women 70 years of age. In a population of women who successfully sued for failure to diagnose breast cancer, almost 70% had a normal or equivocal mammogram.

Sources:

1. Kern KA. The delayed diagnosis of symptomatic breast cancer. In: Bland KA, Copeland EM (Eds.). *The Breast: Comprehensive Management of Benign and Malignant Disease*. 2nd Edition. Philadelphia, PA: WB Saunders Company, 1998, pp. 1588-1631.
2. Physician Insurers Association of America. *Breast Cancer Study*. Lawrenceville, NJ: Physician Insurers Association of American, 1995.



Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999. Modified from Kern KA. The delayed diagnosis of symptomatic breast cancer. In Bland KA, Copeland EM (Eds.). *The Breast: Comprehensive Management of Benign and Malignant Disease*. 2nd edition. Chapter 94, figure 94-12. Philadelphia, PA: W.B. Saunders Company, 1998. Used with permission.

SLIDE 130

Kern has proposed a "triad of error" for the misdiagnosis of breast cancer. Although each is by no means necessary for diagnostic delay, together they account for 75% of cases filed for failure to diagnose breast cancer. This section of the curriculum is meant to outline the principles used to achieve a timely diagnosis of breast cancer while simultaneously avoiding needless work-up and/or referral.

Source:

Kern KA. The delayed diagnosis of symptomatic breast cancer. In: Bland KA, Copeland EM (Eds.). *The Breast: Comprehensive Management of Benign and Malignant Disease*. 2nd Edition. Philadelphia, PA: WB Saunders Company, 1998, pp. 1588-1631.

Types of Breast Masses

I. Benign - Aberrations of Normal Development and Involution (ANDI)

- Cyst
- Fibroadenoma
- Fibrocystic mass

II. Malignant

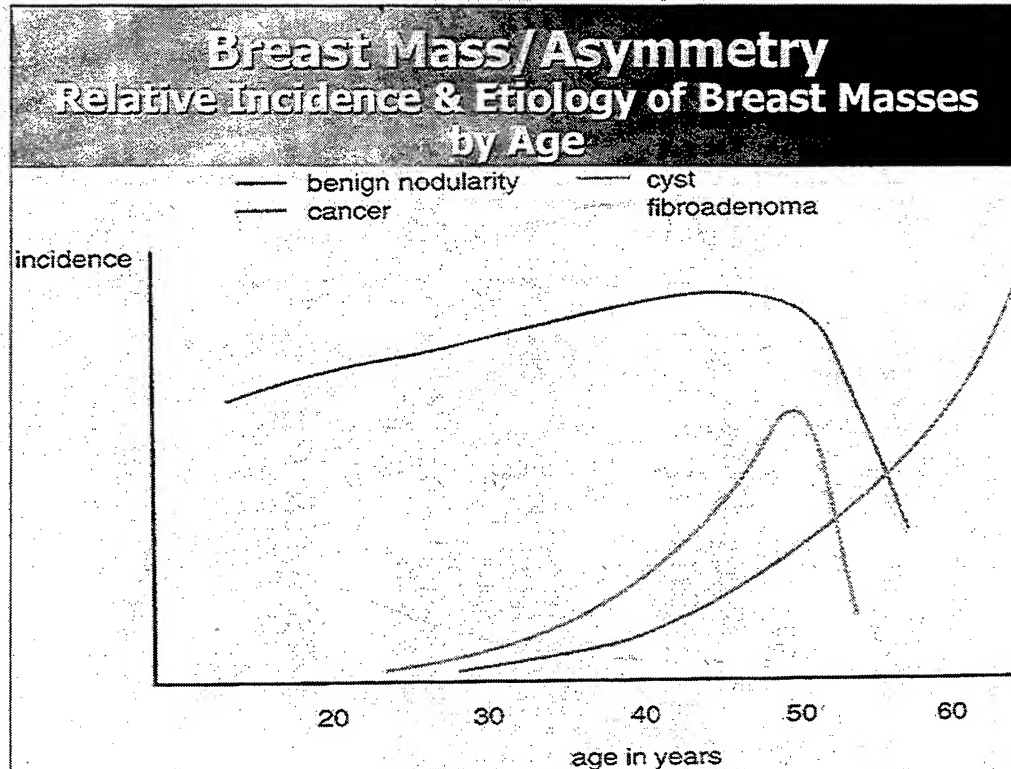
Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 131

Before discussing the management of breast masses, it will be helpful to review the classification. Whether a thickening or a dominant mass, there are four basic types of palpable abnormalities that occur in a woman's breast. These include: 1) a cyst, 2) a fibroadenoma, 3) a fibrocystic mass, and 4) cancer.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3, No. 5.
<http://www.medscape.com> (see instructions in Appendix 10).



Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000. Modified from Mansel RE, Rundred NJ (Eds.), *Color Atlas of Breast Diseases*, Chapter 6, figure 6-1. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 132

This slide demonstrates the relative incidence by age of the four common etiologies of breast masses. Note that:

- 1) Fibroadenomas are common in adolescents and women in their 20s and 30s.
- 2) Cysts are most common in women in their 40s.
- 3) Benign breast nodularity is common at all premenopausal ages and uncommon after age 55.
- 4) In women above age 55, the most common etiology of a breast mass is cancer.

Source:

Breast Lumps. In: Mansel RE, Rundred NJ (Eds.), *Color Atlas of Breast Diseases*. London: Times Mirror International Publishers Limited, 1995.



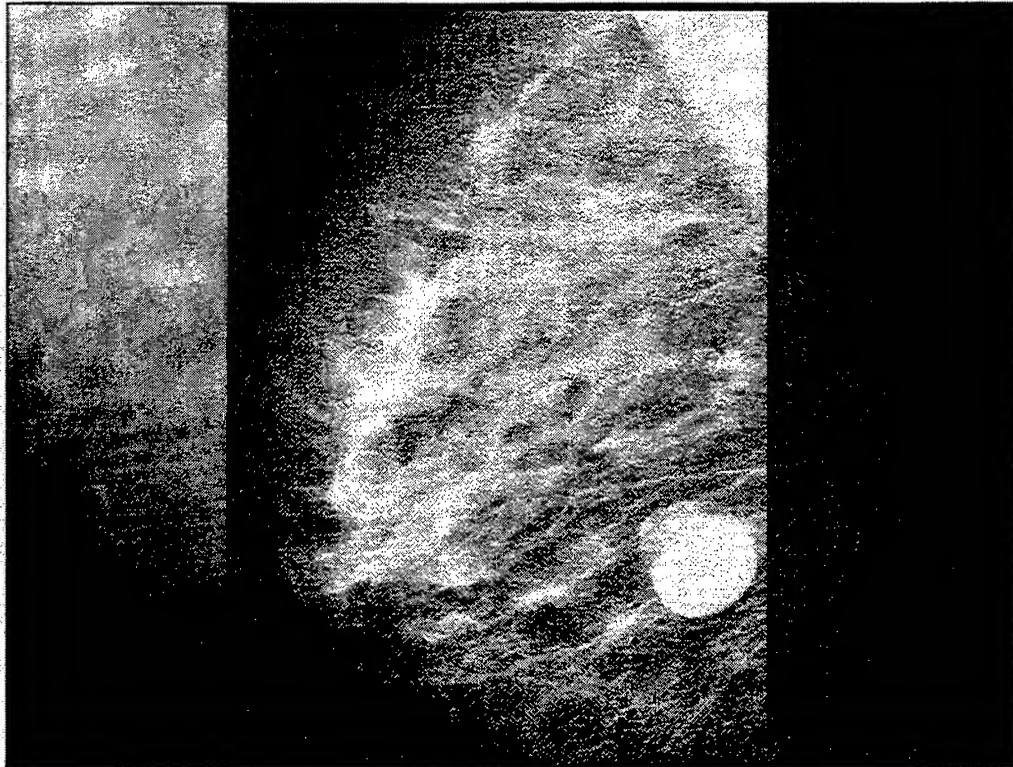
Slide Credit: from Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast – Concepts and Clinical Management*, Chapter 9, figure 9.1. London: Baillier Tindall, 1989. Used with permission.

SLIDE 133

This is a cyst present on the underside of removed breast tissue. A breast cyst is similar to a cyst elsewhere in the body; it represents a fluid-filled structure which is benign. A breast cysts is a process of lobular involution and as such, is found mostly in perimenopausal women. It is uncommon to find cysts present in women before the age of 35. A cyst can exist in postmenopausal women, but is uncommon unless the woman is taking hormone replacement therapy. Keep in mind the gross appearance of a cyst. Because the sac is under tension, it cannot be distinguished from a solid mass by physical examination. Breast cysts are not usually removed in the operating room, but instead, are drained therapeutically in the office.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. *Medscape Women's Health*, 1998: Vol 3. No. 5.
<http://www.medscape.com> (see instructions in Appendix 10).



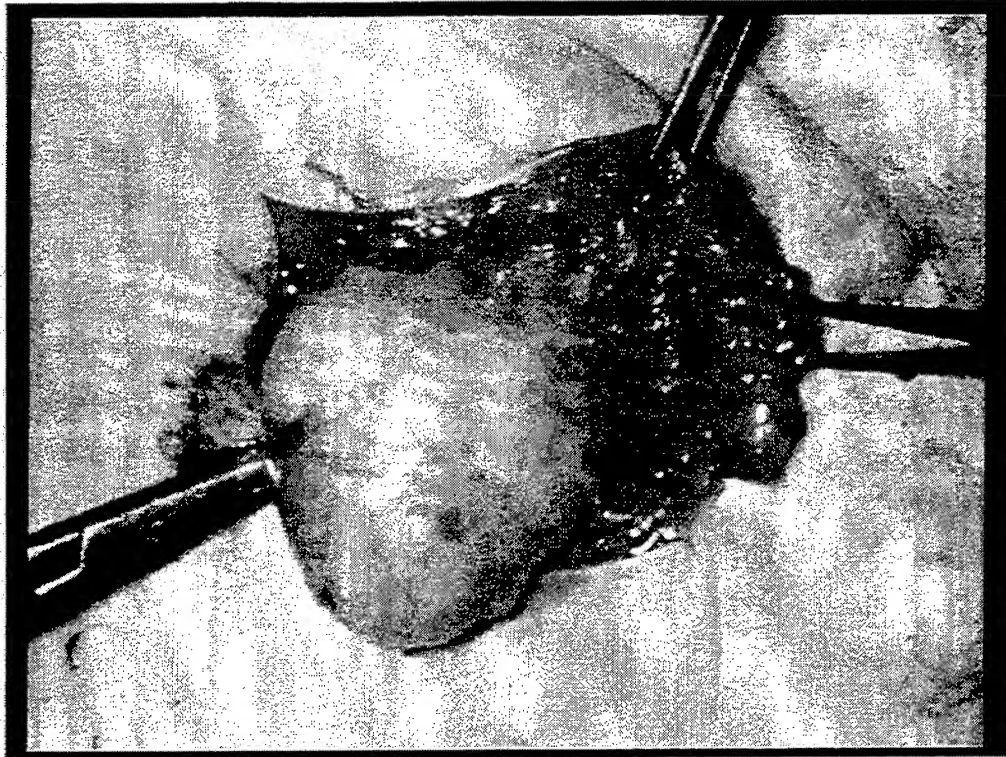
Slide Credit: Tabar L, Dean P. *Teaching Atlas of Mammography*, 2nd Edition. New York, NY: Thieme Medical Publishers, Inc, 1983, plate 27A. Used with permission.

SLIDE 134

This mammogram demonstrates a round, smooth-walled density which could represent a fluid-filled or solid structure. The differentiation can be made by neither CBE nor mammography.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. *Medscape Women's Health*, 1998: Vol 3. No. 5.
<http://www.medscape.com> (see instructions in Appendix 10).



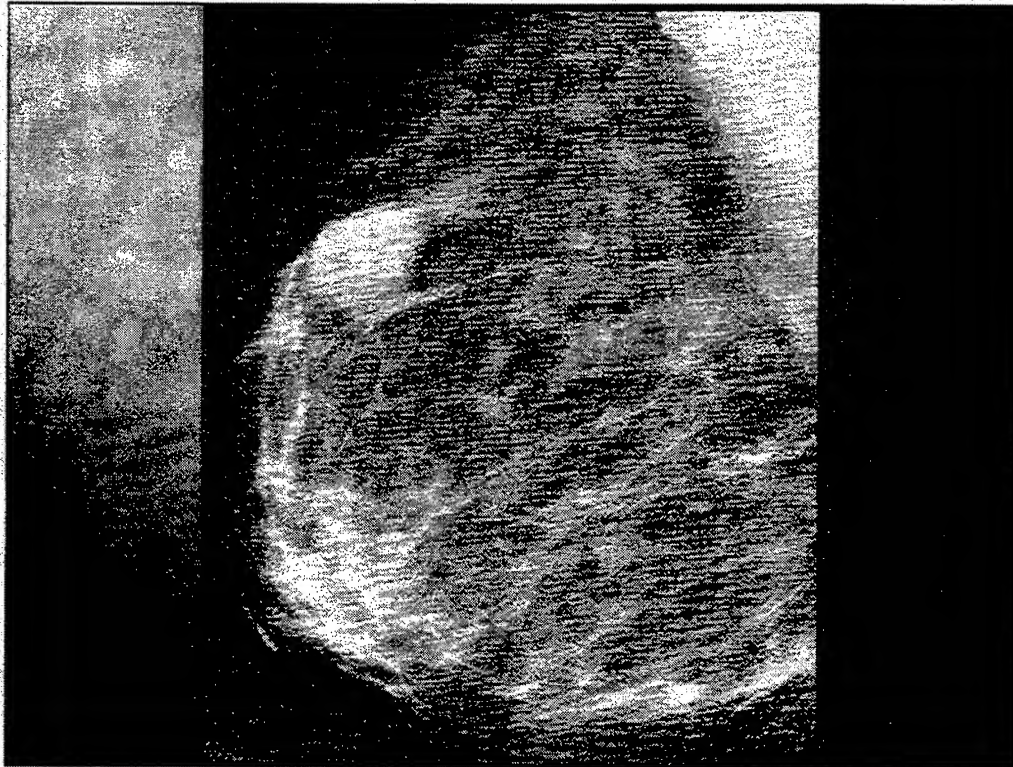
Slide Credit: from Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast – Concepts and Clinical Management*, Chapter 7, figure 7.5. London: Baillier Tindall, 1989. Used with permission.

SLIDE 135

This slide represents a fibroadenoma being removed in the operating room. A fibroadenoma is a benign solid mass that occurs most frequently in young women, beginning with adolescence. These masses are usually quite mobile on physical examination and represent a benign process of encapsulated connective tissue proliferation that incorporates epithelial elements within it. The mass has a smooth or lobulated characteristic on palpation.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. *Medscape Women's Health*. 1998: Vol 3. No. 5.
<http://www.medscape.com> (see instructions in Appendix 10).



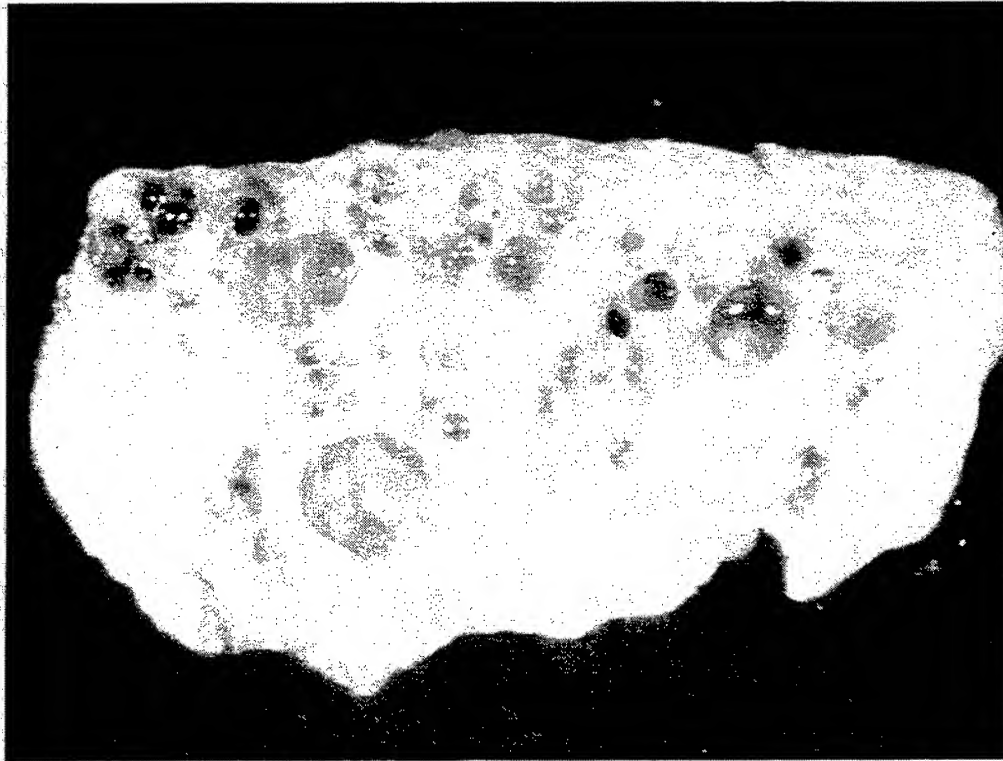
Slide Credit: Tabar L, Dean P. *Teaching Atlas of Mammography*, 2nd Edition. New York, NY: Thieme Medical Publishers, Inc, 1983, plate 33B. Used with permission.

SLIDE 136

This slide represents a mammographic finding of a fibroadenoma. Notice that it appears exactly like the cyst in the previous mammogram. The radiologist will also read this report as a smooth-walled density consistent with a cyst or a fibroadenoma.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. *Medscape Women's Health*, 1998: Vol 3. No. 5.
<http://www.medscape.com> (see instructions in Appendix 10).



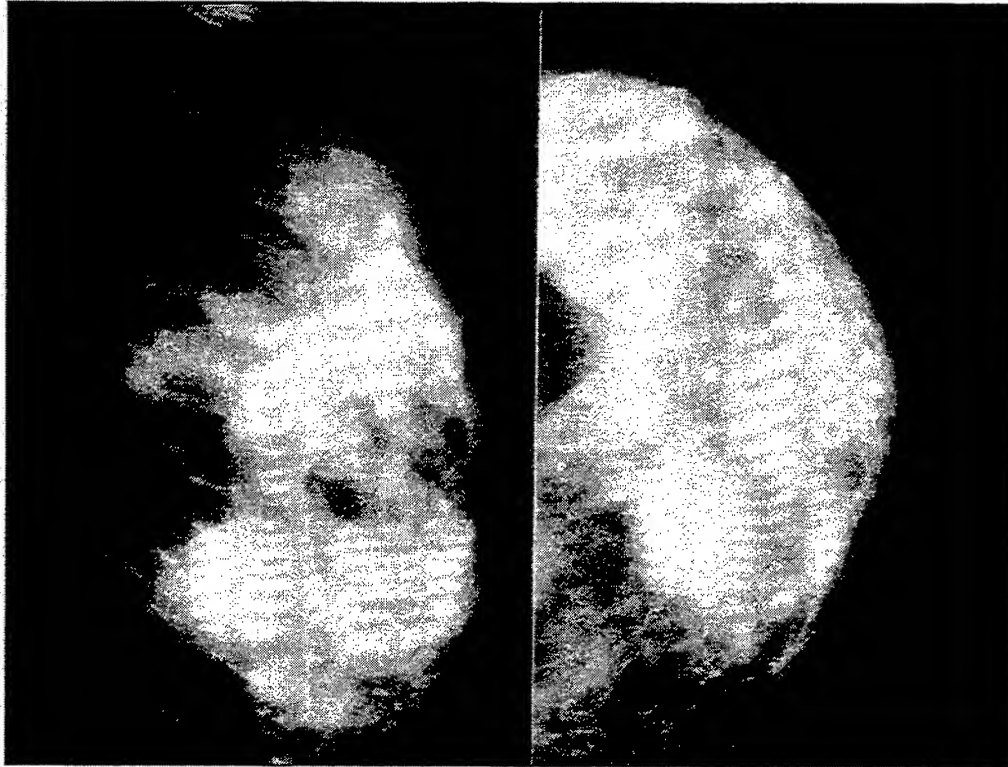
Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.
(Slide from personal collection of Janet Rose Osuch M.D., M.S.)

SLIDE 137

This is an example of fibrocystic change in the breast. Note the presence of several microcysts within the breast structure. The white portions on the slide represent the parenchymal and fibro-connective tissue. Women are often very fearful about the diagnosis of any type of fibrocystic change. Physicians often use this diagnosis to denote nodularity, but it must be made clear to the patient that this is an all - encompassing term which need not be feared. When it is made clinically rather than pathologically, reference is literally being made to nodularity which does not appear to be cancer clinically. It is often helpful to explain this to patients using this phrase. Fibrocystic change is very common in premenopausal women and in some postmenopausal women on hormone replacement therapy, owing to the influence of ovarian hormones on the physiology of breast tissue. Unfortunately, it is not possible to definitively distinguish a fibrocystic mass from a malignant one by physical examination or by radiologic studies. It is especially dangerous to attribute a changing breast examination to fibrocystic change in postmenopausal women, who should not be undergoing dynamic breast changes because ovarian function has ceased.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health. 1998; Vol 3, No. 5. <http://www.medscape.com> (see instructions in Appendix 10).



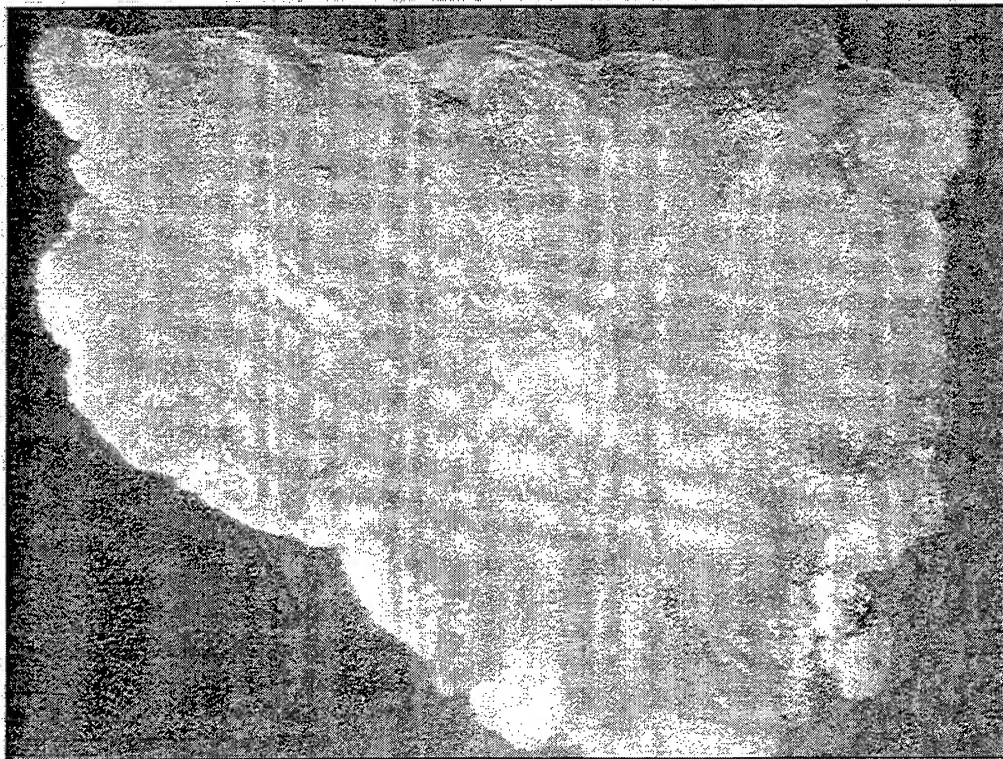
Slide Credit: From slide – lecture series, *Breast Imaging: A Guide for Clinicians*. Sandowsky NL, Fieg SA, McLelland R. American College of Radiology, Reston, VA, Slide No. 26A. Used with permission.

SLIDE 138

This is a mammogram demonstrating dense tissue with multiple cysts. It is very difficult to distinguish normal from abnormal findings in this mammogram.

Source:

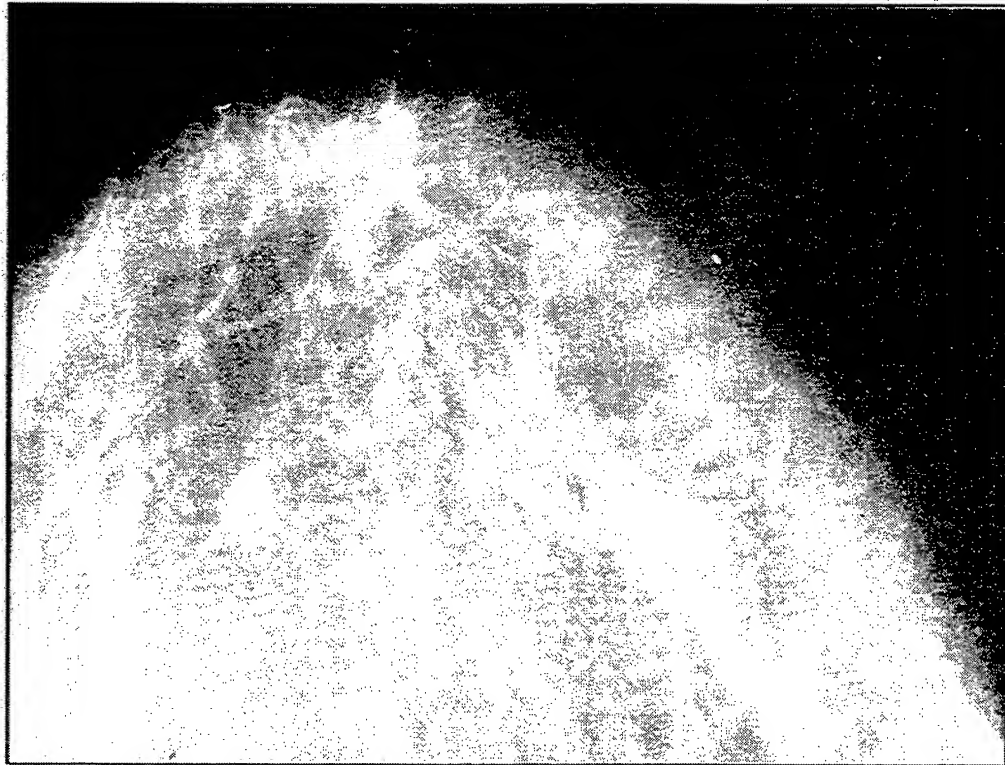
Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. *Medscape Women's Health*, 1998: Vol 3. No. 5.
<http://www.medscape.com> (see instructions in Appendix 10).



Slide Credit: from Blamey R, Evans A, Ellis I, et al. (Eds.). *Atlas of Breast Cancer*. Figure 30. Hampshire, UK: Merit Publishing International, 1994. Used with permission.

SLIDE 139

The white central area represents a spiculated mass and is malignant. It is surrounded by adipose tissue, a common finding in post-menopausal women. Any breast mass in a post-menopausal woman should be assumed to represent cancer until proven otherwise. Hormone replacement therapy may influence this caveat, as cysts are slightly more common in this setting.



Slide Credit: Tabar L, Dean P. *Teaching Atlas of Mammography*, 2nd Edition. New York, NY: Thieme Medical Publishers, Inc, 1983, plate 59C. Used with permission.

SLIDE 140

This is how that mass would appear mammographically. Note the spiculated density in the mammogram, and the lucent appearance of the surrounding adipose tissue.

Breast Mass/Asymmetry

Initial Evaluation

- **History and CBE**
- **Mammogram**
- **Fine needle aspiration
and/or referral**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 141

The complete evaluation of a breast mass involves three steps. They include:

- 1) A history and clinical breast exam
- 2) A mammogram before or after aspiration
- 3) A fine needle aspiration and/or referral

Breast Mass/Asymmetry *HISTORY*

***Step 1:* Read presenting
complaint**

***Step 2:* Employ a systematic
method of inquiry**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 142

Many physicians rely on office assistants to room patients and solicit the reason for the visit. In the midst of busy days with many interruptions, the note written by the assistant will sometimes be inadvertently overlooked by the clinician. This is a dangerous habit from a risk management standpoint. Many women find it easier to tell an assistant, rather than a clinician, about a problem that causes them fear. If the clinician does not address the problem, the woman can easily assume that the clinician does not perceive the problem as significant and will do nothing to address it further until it is impossible to deny its significance.

Every clinician should have a systematic method to address a breast mass as a presenting complaint.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5.
<http://www.medscape.com> (see instructions in Appendix 10).

Breast Mass/Asymmetry

FOCUSED HISTORY

- **Location**
- **Method of discovery**
- **Size**
- **Duration**
- **Hormonal influences**
- **Characteristics of tenderness**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 143

The essential components of the inquiry include: (1) **Location:** Ask the woman to point to her area of concern with one finger. Document this area on the physical examination record pictorially, with an "X". (2) **Method of discovery:** Establish how familiar the woman is with her own breast examination. How often does the woman perform breast self-examination (BSE)? Did she discover the lump during BSE or by accident? Was it found in the supine position, standing in the shower, or by a different method? The evaluation may be very different if a patient is not sure that a mass is present and rarely does BSE, as opposed to a patient doing regular BSE who feels a difference on her exam compared to baseline. (3) **Size:** How big is the lump currently? Liken the size to familiar items, such as a pea, a grape, a walnut. (4) **Duration:** When was the lump first found? Has it changed since first date of discovery? (5) **Hormonal influences:** What is the woman's ovulatory status? Is she premenopausal? If so, does the mass change depending on the phase of her ovulatory cycle? Is she on hormone replacement therapy? (6) **Tenderness:** Is the mass tender? Does the tenderness change with the ovulatory cycle if she is premenopausal?

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health. 1998; Vol 3. No. 5. <http://www.medscape.com> (see instructions in Appendix 10).

Breast Mass/Asymmetry

Clinical Breast Exam

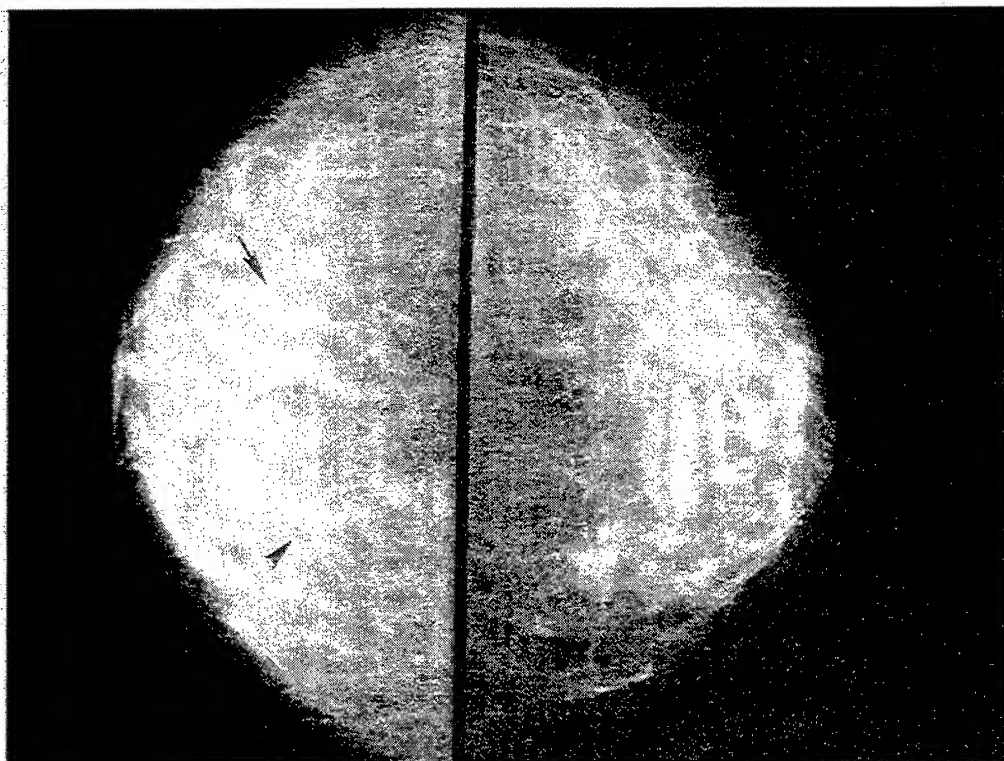
Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 144

Our focus this afternoon will be skill teaching, practice, and evaluation of the clinical breast exam. Many physicians have acknowledged the inadequacy of their medical school experience in learning this skill and request refresher courses. The clinical breast exam will take time to perform correctly, but is one of the most important components of physical exam in the ambulatory patient.

Source:

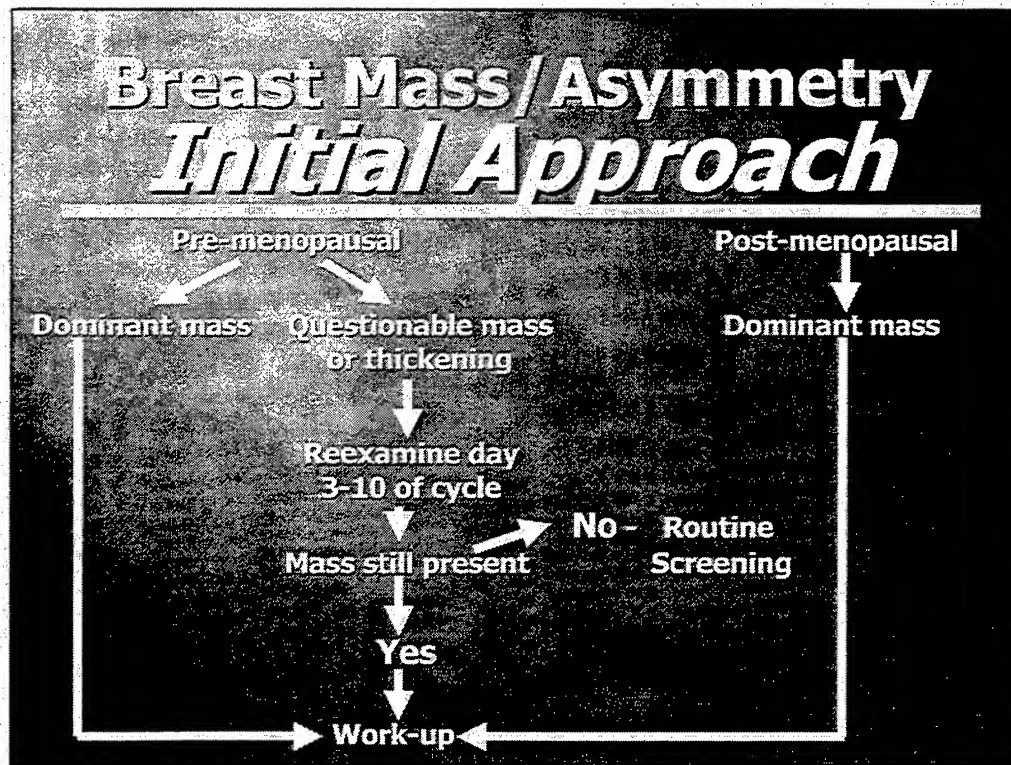
Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. <http://www.medscape.com> (see instructions in Appendix 10).



Slide Credit: From slide – lecture series, *Breast Imaging: A Guide for Clinicians*. Sandowsky NL, Fieg SA, McLelland R. American College of Radiology, Reston, VA, Slide No. 21. Used with permission.

SLIDE 145

This diagnostic mammogram was performed in a woman who presented with a breast mass. In the upper portion of the slide, the palpable mass which proved to be a fibroadenoma is imaged. Also imaged is a non-palpable abnormality which proved to be a small infiltrating ductal carcinoma. This would have been missed had the mammogram not been ordered.



Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

Modified from Harris JR, Lippman ME, Morrow M, Hellman S, (Eds.). *Diseases of the Breast*, Chapter 5, figure 5.3-1. Philadelphia, PA: Lippincott-Raven, 1996. Used with permission.

SLIDE 146

When a mass or asymmetry is confirmed on CBE, the initial clinical approach is dependent on the ovulatory status of the patient. Subtle abnormalities in premenopausal women are best approached by a repeat exam at the best phase of the menstrual cycle. Many masses resolve under these circumstances. If the mass persists, or if it is dominant, found in the best phase of the cycle, or present in a post-menopausal woman, immediate work-up should be pursued.

Source:

Osuch JR. Abnormalities on physical examination. In Harris JR, Lippman ME, Morrow M, et al., (Eds.), *Diseases of the Breast*. Philadelphia, PA: Lippincott-Raven Publishers, 1996, pp. 110-114.

Breast Mass/Asymmetry

It is impossible to distinguish a cyst from a solid mass by CBE or mammography

Fine Needle Aspiration (FNA)

Purpose: To distinguish a cyst from a solid mass

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 147

The clinician's single most important role in a patient who presents with a breast mass is to establish the etiology of the mass as cystic or solid. This is impossible by either CBE or mammography. FNA refers to the insertion of a small needle into a mass with subsequent aspiration of its contents. FNA is possible using ultrasound guidance, but this is not necessary in the case of palpable masses. If a mass is solely cystic, it will disappear following a complete aspiration.

Ultrasound alone can also distinguish between cysts and solid masses, and as we have discussed, is the only method available for distinguishing the two in non-palpable abnormalities. For a palpable mass the most expedient and cost-effective method is needle aspiration.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health. 1998: Vol 3. No. 5.
<http://www.medscape.com> (see instructions in Appendix 10).

Breast Mass/Asymmetry

Reasons for FNA:

- 1. To distinguish a cyst from a solid mass**
- 2. To accomplish an expedient diagnosis**
- 3. To accomplish therapeutic drainage**
- 4. To establish the etiology of a cyst as benign**
- 5. To provide pain relief in a symptomatic cyst**
- 6. *To provide for an optimal CBE free of interfering masses***

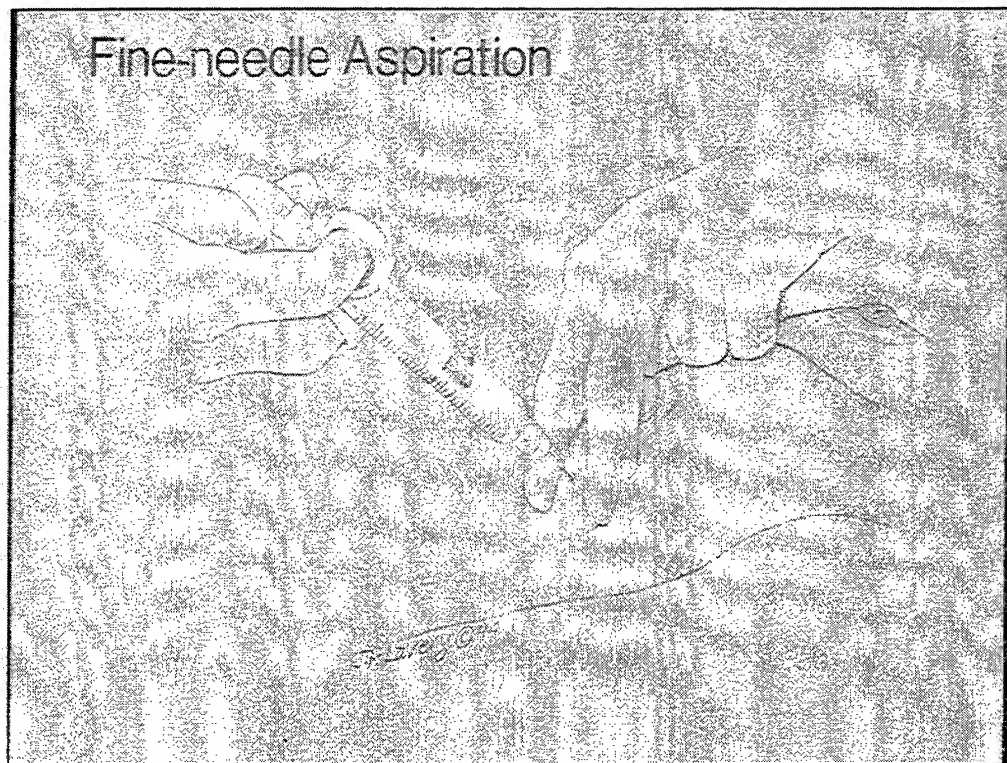
Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 148

Reasons for needle aspiration of a breast mass include the following: (1) FNA distinguishes a cyst from a solid mass; (2) it accomplishes an expedient diagnosis; (3) it accomplishes therapeutic drainage of a breast cyst; (4) FNA establishes the etiology of a cyst as benign; (5) it provides relief of pain in the symptomatic cyst, because cysts that are under tension are often tender, and most importantly; (6) FNA provides for an optimal clinical breast examination free of interfering masses.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998; Vol 3. No. 5. <http://www.medscape.com> (see instructions in Appendix 10).



Slide Credit: Slide No. 197 from Osuch JR, Dell DL, Sleighter S. *Breast and Cervical Cancer Education for Primary Care Providers*. Alexandria, VA: American Medical Women's Association, 1994, Joyce Lavery, MFA, CMI. Used with permission.

SLIDE 149

A cyst aspiration is a very simple procedure that can be done in the office setting. It involves the placement of a 21-23-gauge needle attached to a 5 cc - 10 cc syringe into the mass, with vacuum aspiration applied manually during the procedure. If the mass is cystic, fluid will fill in the barrel of the syringe and the mass will disappear. It is very important to palpate for total mass disappearance and to ensure that there is complete symmetry between one breast and the other at the end of the procedure.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. *Medscape Women's Health*, 1998: Vol 3, No. 5.
<http://www.medscape.com> (see instructions in Appendix 10).



Slide Credit: from Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast – Concepts and Clinical Management*, Chapter 9, figure 9.5. London: Baillier Tindall, 1989. Used with permission.

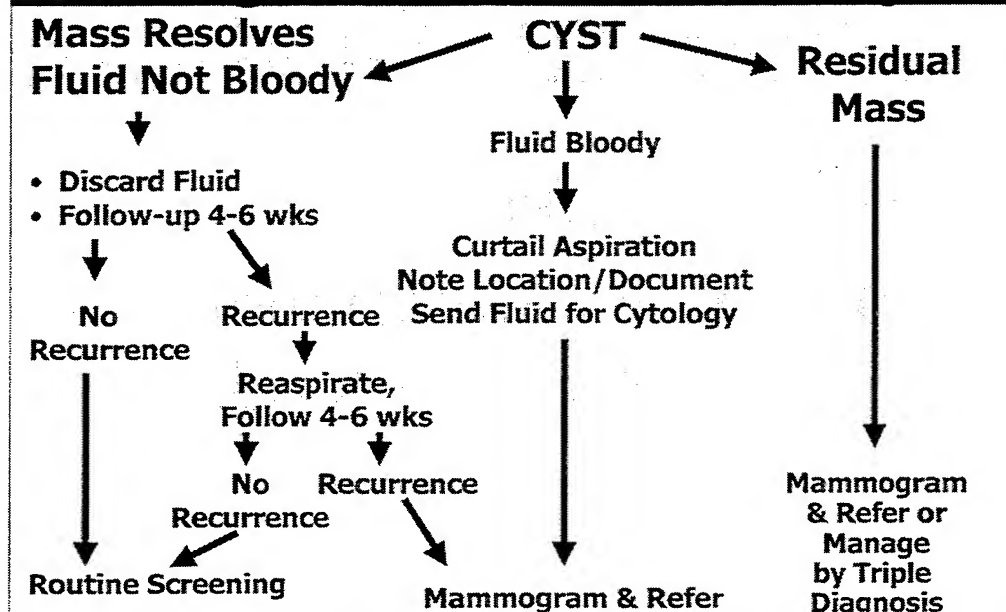
SLIDE 150

This slide demonstrates the apocrine cell lining of one wall of a cyst. It is important to compress the cyst during aspiration to assure that the walls of the cyst are in contact with one another at the end of the aspiration and that the cyst has been emptied of fluid. This maneuver increases the chances that the cyst will not recur.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. *Medscape Women's Health*, 1998: Vol 3. No. 5.
<http://www.medscape.com> (see instructions in Appendix 10).

Breast Mass/Asymmetry Management of a Breast Cyst



Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

Modified from Harris JR, Lippman ME, Morrow M, Hellman S, (Eds.). *Diseases of the Breast*, Chapter 5, figure 5.3-2. Philadelphia, PA: Lippincott-Raven, 1996. Used with permission.

SLIDE 151

If the mass disappears following needle aspiration, the fluid can be discarded. The patient is then asked to come back to the clinic 4 to 6 weeks later. If there has been no recurrence of the mass, the patient is put on routine follow-up schedule. If the cyst recurs in the same location, it can be re-aspirated, but if it recurs after a second 4 to 6 week follow-up, this is an indication for referral to rule out intracystic carcinoma. Some may choose to refer after the first cyst recurrence. If the initial fluid that was aspirated is grossly bloody, the fluid is sent for cytology and the patient referred to rule out intracystic carcinoma. It is important to know that if bloody fluid is encountered, the aspiration should be stopped so that the consulting physician knows the exact location of the bloody cyst. It is possible for a residual mass to be present on post-aspiration examination or follow-up. Under these circumstances, the mass should be managed as any solid mass.

Source:

Osuch JR. Abnormalities on physical examination. In: Harris JR, Lippman ME, Morrow M, et al (Eds.). *Diseases of the Breast*. Philadelphia, PA: Lippincott-Raven Publishers, 1996. pp. 110-114.

Breast Mass/Asymmetry
Breast Cyst
Indications to Analyze Cyst Fluid:

- **Bloody Fluid**
- **Fluid from postmenopausal woman not on HRT**

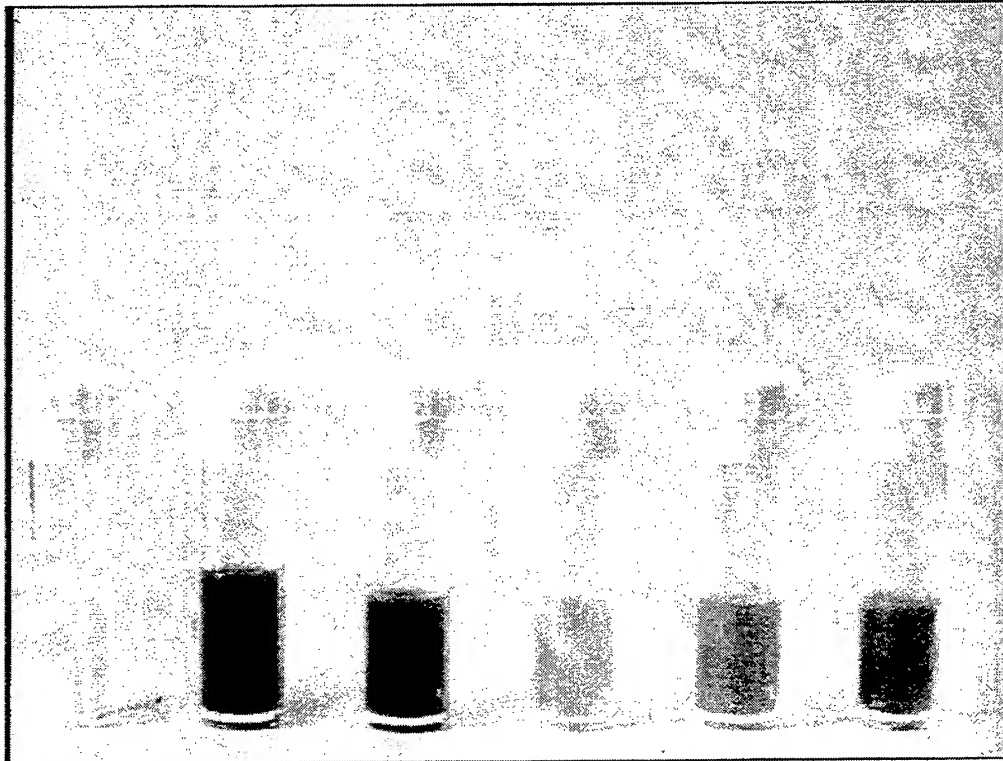
Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 152

If the fluid is grossly bloody, it should be analyzed. If a cyst is aspirated in a postmenopausal woman and she is not on hormone replacement therapy, the fluid is also commonly analyzed. No matter what the cytology demonstrates; however, further evaluation will be necessary, usually through referral. In all other patients the fluid can be discarded.

Source:

Osuch JR. Abnormalities on physical examination. In: Harris JR, Lippman ME, Morrow M, et al (Eds.). *Diseases of the Breast*. Philadelphia, PA: Lippincott-Raven Publishers, 1996, pp. 110-114.



Slide Credit: from Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast – Concepts and Clinical Management*, Chapter 9, figure 9.3. London: Baillier Tindall, 1989. Used with permission.

SLIDE 153

The color of the fluid removed from a cyst covers a wide spectrum. On the far left is fluid typical of a galactocele in a lactating woman. The other vials contain fluid from a variety of cysts. In general, the darkness of the cyst fluid corresponds to the age of the cyst. Cysts of recent onset are a serous-colored, while older ones are darker. The changes in pigments occur when the epithelial lining of a cyst degenerates, and the cells fall into the cystic fluid.

Source:

Breast anatomy and physiology. In: Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management*. London: Bailliere Tindal, 1989, pp.93-101.

Breast Mass/Asymmetry

***Never* tell a patient
"Don't worry, it's just a cyst."**



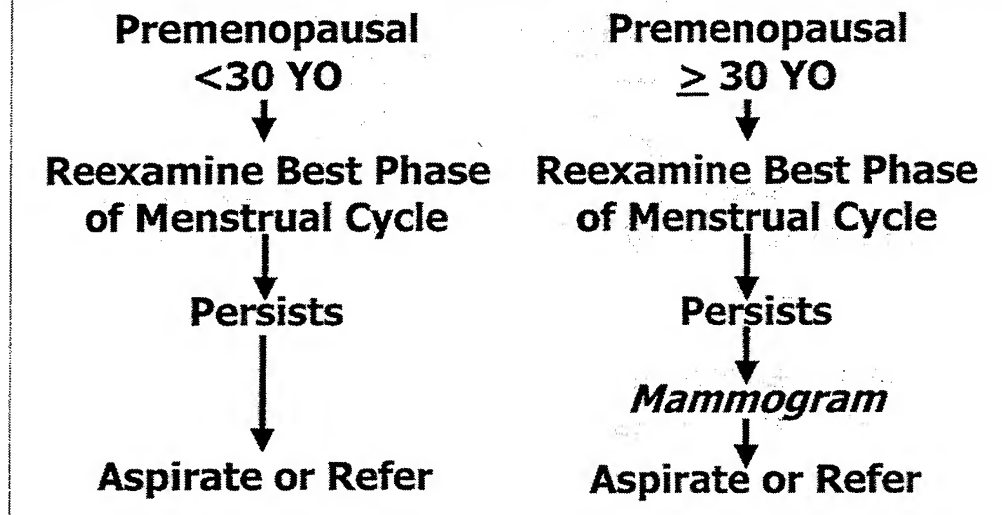
Aspirate To Prove It!

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 154

Remember that the only way to document that a palpable abnormality is a cyst is by needle aspiration or ultrasound, with the former preferred. Many anxious weeks experienced by women could be eliminated if primary care physicians became comfortable with this simple in-office procedure.

Breast Mass/Asymmetry: *Mammography*



Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University. 2000.

SLIDE 155

Whether mammography is done for a mass or other breast symptoms, certain guidelines apply to its appropriate application. On the left is an algorithm for women <30 years of age. Note that this algorithm does not include a mammogram. Instead, a woman would be asked to return at the best phase of her menstrual cycle for an examination, and if the mass persists at that time, one of two courses is possible. The primary provider can aspirate the mass, or the patient can be sent to a surgeon who will perform this procedure.

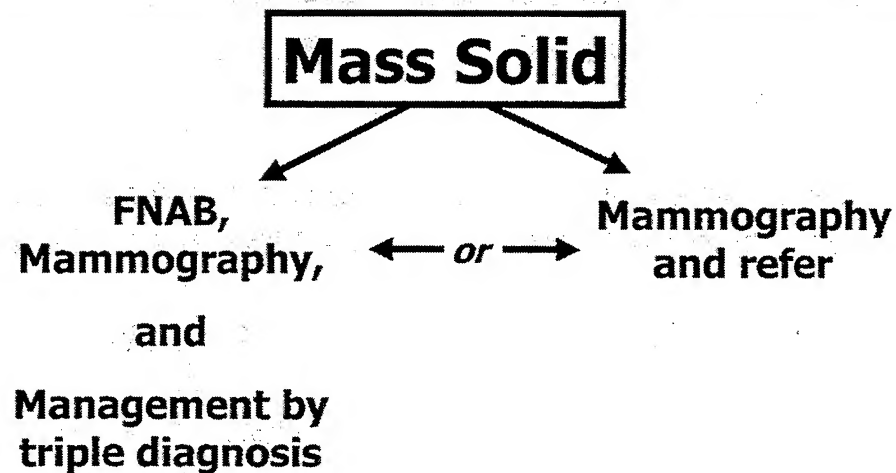
The course is the same for women ≥ 30 years of age who are premenopausal, except that they are asked to get a mammogram. The reason for the differentiation is that mammograms are unlikely to be helpful in women less than 30 years of age, as discussed previously.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998; Vol 3, No. 5. <http://www.medscape.com> (see instructions in Appendix 10).

Breast Mass/Asymmetry

SOLID MASS



Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 156

Aspiration will often establish a mass to be solid rather than cystic. Three characteristics suggest the presence of a solid mass: (1) the lack of fluid in the syringe barrel, (2) the solid nature of the aspirate, and (3) persistence of the mass following aspiration. The next portion of the curriculum will address the management of a solid mass or asymmetry.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5.
<http://www.medscape.com> (see instructions in Appendix 10).

Breast Mass/Asymmetry: ***Solid Mass: Diagnostic Approach***

- **Open biopsy**
- **Core biopsy**
- **Fine needle aspiration biopsy
(FNAB) and management by
triple diagnosis**

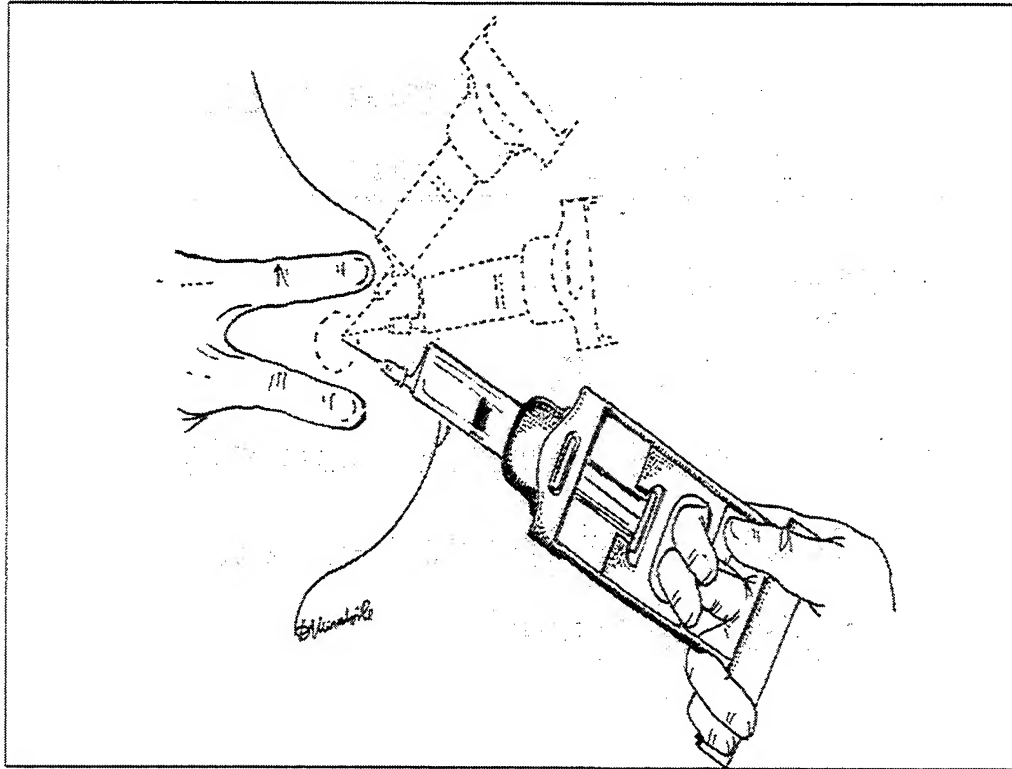
Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 157

Options for work-up of solid masses include open biopsy, core biopsy, or fine needle aspiration biopsy. Note that each of the approaches includes the word **BIOPSY**. FNAB refers to the aspiration of a solid mass in order to obtain cytopathologic representation of its contents. The distinction between simple FNA and FNAB is extremely important. Whereas FNA is an either/or phenomenon (either a mass is cystic or solid), FNAB requires knowledge of the technical aspects of the procedure, an aspirator experienced in obtaining an optimal sampling of cells, a skilled cytopathologist for cellular interpretation, and interpretive knowledge of the many pitfalls inherent in the technique.

Source:

Osuch JR. Abnormalities on physical examination. In: Harris JR, Lippman ME, Morrow M, et al (Eds.). *Diseases of the Breast*. Philadelphia, PA: Lippincott-Raven Publishers. 1996, pp. 110-114.



Slide Credit: from Catania S, Ciatto S (Eds.). *Breast Cytology in Clinical Practice*, Chapter 3, figure 3.24. London: Martin Dunitz Ltd., 1992. Used with permission.

SLIDE 158

When fine needle aspiration biopsy is done, the same instrumentation is used as for cyst aspiration. However, instead of fluid being aspirated into the barrel of the syringe, the sample is contained within the needle. The needle is passed into the lesion several times in order to sample it to obtain an adequate number of cells. This procedure is commonly done only by personnel who are well trained in the technique and who have cytopathologists comfortable with slide interpretation.

Source:

Catania S, Ciatto S. Breast cytology: Instruments and techniques. In: Catania S, Ciatto S (Eds.), *Breast Cytology in Clinical Practice*. London: Martin Dunitz Ltd., 1992.

Breast Mass/Asymmetry ***Solid Mass: Fine Needle*** ***Aspiration Biopsy (FNAB)***

False positive rate - 0.17%

Average false-negative rate - 10.00%
(Range - 0.4% - 35%)

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 159

The false-positive rate for fine needle aspiration biopsy is low, averaging 0.17%. The false-negative rate, however, averages about 10%, and has a range between 0.4% and 35%.

Source:

Layfield LJ, Glasgow BJ, Cramer H. Fine needle aspiration in the management of breast masses. *Pathol Annu* 1989; 24:23-62.

Breast Mass/Asymmetry

Solid Mass: FNAB

Reasons for False-Negative Results:

- **Inadequate sampling**
- **Lack of target tissue sampling**
- **Tumors with extensive fibrosis/necrosis**
- **Well-differentiated tumors**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 160

Inadequate sampling represents the most common reason for a false-negative result and is usually a result of inadequate experience on the part of the aspirator. If the clinician plans to use FNAB in the diagnostic evaluation of a breast mass, the method of reporting inadequate cellularity must be explored with the cytopathologist. If inadequate cellularity is reported, a repeat FNAB or open biopsy should be done.

Other reasons for false negative results have been cited, including lack of target tissue sampling, technical problems with slide preparation or reading, tumors with extensive fibrosis or necrosis, and well-differentiated tumors. Because of the latter problem, *any FNAB interpreted as atypical will require an open biopsy for diagnosis*. However, full awareness of all of these diagnostic pitfalls will still not achieve 100% accuracy with this technique.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998; Vol 3, No. 5. <http://www.medscape.com> (see instructions in Appendix 10).

Breast Mass/Asymmetry

Solid Mass: Triple Diagnosis

- 1. CBE**
- 2. Mammography**
- 3. FNAB**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 161

In order to increase diagnostic accuracy, the principles of "triple diagnosis" have been used. "Triple diagnosis" refers to the application of three steps to evaluate a breast mass: (1) clinical assessment by palpation, (2) results of mammography, and (3) results of FNAB. A principle of this evaluation method is that if any one of the variables is "suspicious", then open biopsy is warranted.

The false-negative rate of CBE, mammography, and FNAB will need to be kept in mind when applying this method. In circumstances in which the radiologic study does not actually demonstrate the lesion, it is not known if it is safe to use the technique of triple diagnosis and it is safer to simply biopsy persistent masses.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998; Vol 3. No. 5.
<http://www.medscape.com> (see instructions in Appendix 10).

Breast Mass/Asymmetry

Solid Mass: Triple Diagnosis

- **If all three components are benign, there is a 99% chance that the lesion is benign**
- **Suggested follow up:**
Every 3 months until resolution of mass or for at least 1 year.

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 162

When all three components of triple diagnosis are interpreted as benign, there is about a 99% chance the lesion is benign. A patient should be given this fact in order to decide between biopsy and follow up. If she chooses the latter, it is suggested that the first visit occur 3 months later. Subsequent visits should be 3 months after that until the lesion has resolved or has remained stable for at least 1 year. Using this technique, a 1% risk of missing cancer on the initial evaluation must be accepted.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5.
<http://www.medscape.com> (see instructions in Appendix 10).

Breast Mass/Asymmetry **Interpretation of** **Mammography and Aspiration**

**Ensure that aspirated mass
is in same location as any
imaged mammographic
density consistent with a
mass.**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University. 2000.

SLIDE 163

There is an important caveat in interpretation of mammography and aspiration of a palpable mass, whether done as FNA or FNAB. It is very important to ensure that an aspirated mass is in the same location as any imaged mammographic density. If concern exists that a palpable lesion does not correlate with the film, then additional consultation with the radiologist, or examination of the films is suggested. If one does not make this correlation, it is possible to aspirate a mass and still have a mammographic abnormality left behind which has not been evaluated.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5.
<http://www.medscape.com> (see instructions in Appendix 10).

Breast Mass/Asymmetry

Timing of Mammography and Aspiration

**If aspiration is done prior
to mammography, avoid
radiographic imaging
for 2-3 weeks to avoid
false-positive results.**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 164

If an aspiration is done prior to mammography, then the radiologic imaging should be avoided for 2-3 weeks. This is because hematomas can form when aspiration is done, and can cause false positive mammographic results visible as a spiculated density.

Algorithms summarizing the initial approach to a breast mass, management of a breast cyst, and management of a solid mass by triple diagnosis can be found in Appendices 5a, 5b, and 5c.

Source:

Sickles EA, Klein DL, Goodson WH, Hunt TK. Mammography after needle aspiration of palpable breast masses. *Am J Surg* 1983;145:395-397.

Breast Mass/Asymmetry ***Patient-Discovered Mass Not Confirmed on CBE:***

- **CBE interpretation can be difficult**
- **Cannot always palpate what a patient may perceive internally**
- **CBE may fluctuate in premenopausal women**
- **Difficult for patients to differentiate localized pain from a mass**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 165

CBE interpretation can be difficult, and it is not always possible to palpate what the patient may perceive as “something different”. An ovulating woman’s examination can change, depending on ovarian hormone fluctuations. In addition, patients often have their attention drawn to a particular area because of breast pain. It can be difficult for a patient to distinguish pain from a breast mass on self-examination. The acknowledgement that “Failure to be impressed with clinical findings” was the single most common clinician error found in the Physicians Association of America (PIAA) study makes it important to have a systematic approach to this problem.

Sources:

1. Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women’s Health, 1998; Vol 3, No. 5. <http://www.medscape.com> (see instructions in Appendix 10).
2. Physician Insurers Association of America. *Breast Cancer Study*. Lawrenceville, NJ: Physician Insurers Association of America, 1995.

Breast Mass/Asymmetry *ALWAYS DOCUMENT*

- **A careful history**
- **The location of the patient-discovered abnormality**
- **Standard CBE results compared to BSE results**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 166

After the patient identifies her specific areas of concern, it is extremely important that the following components be documented:

- A careful history
- The location of the patient-discovered abnormality
- The CBE results using both standard technique examination and in the position in which the patient found the mass.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health. 1998: Vol 3. No. 5.
<http://www.medscape.com> (see instructions in Appendix 10).

Breast Mass/Asymmetry
Patient-Discovered Mass
Not Confirmed on CBE:

**Ask patient to point to the
lump with one finger**



**Ask patient to palpate the
abnormality**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 167

Since many women are fearful that they may have a mass but are not sure that they have one, it is important for the provider to document exactly where the woman perceives her breast mass to be located. This is most easily done by asking the patient to point to the lump with one finger. If CBE does not confirm the mass, ask the patient to palpate the abnormality herself.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3, No. 5.
<http://www.medscape.com> (see instructions in Appendix 10).

Breast Mass/Asymmetry **If Unable to Confirm Patient- Perceived Abnormality**

- **Ask patient to find abnormality**
- **Palpate breasts both supine and sitting and compare for symmetry**
- **Document that patient agrees with examiner's findings or**
- **If patient has doubts, see in follow-up in 3-6 months or refer**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 168

Many patients discover their abnormality in the shower. When this occurs, it is recommended that the provider palpate the breasts in the sitting position. Remember to examine the mirror-image area in the contralateral breast, and if the findings are similar have the patient perform her own comparison. If the patient remains concerned, see her in follow-up in 3-6 months or refer.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998; Vol 3. No. 5.
<http://www.medscape.com> (see instructions in Appendix 10).

Signs and Symptoms of Breast Disorders:

NIPPLE DISCHARGE

Non-Spontaneous

Spontaneous

Normal Physiology

Pathology

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 169

We will next turn to the symptom of nipple discharge. It should be emphasized that non-spontaneous nipple discharge is a normal physiological phenomenon and of no clinical consequence. Women who present with this symptom require reassurance exclusively; any other work up is costly both financially and emotionally. The symptom of non-spontaneous nipple discharge resolves when nipple compression is avoided.

Source:

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.): *Textbook of Women's Health*. Philadelphia, PA: J.B. Lippincott, 1998, pp. 295-313.

Signs and Symptoms of Breast Disease:

Nipple Discharge

- **Spontaneous**
- **Color**
- **One duct/more than one**
- **Unilateral/bilateral**
- **Duration**
- **Persistent**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

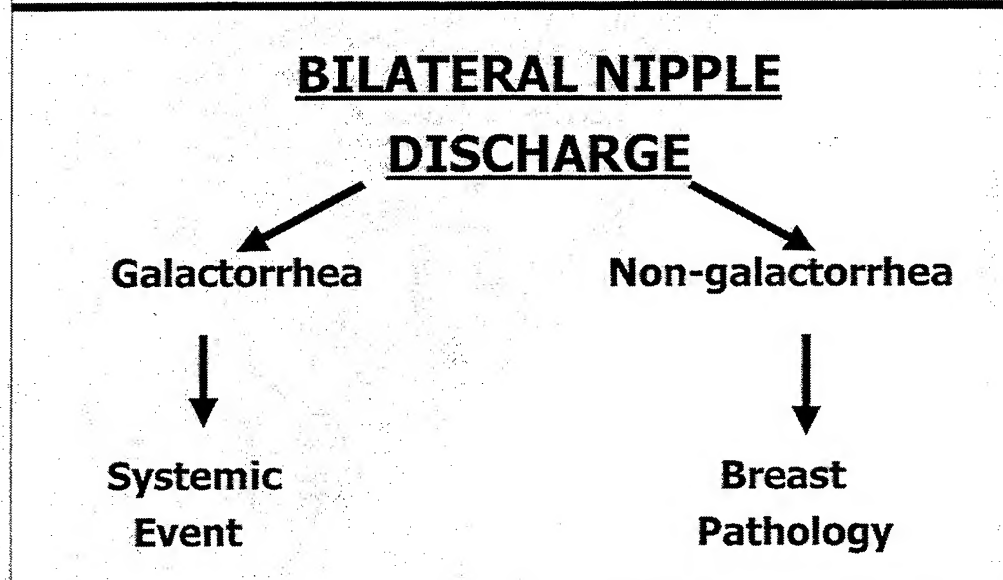
SLIDE 170

To determine if the discharge is spontaneous, ask the patient if it stains her underclothing or bed clothing. If it does, it is significant and requires investigation. Ask about the color, whether one or more ducts is involved, whether it is unilateral or bilateral, when it was discovered, and whether it is persistent.

Source:

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.): *Textbook of Women's Health*. Philadelphia, PA: J.B. Lippincott, 1998, pp. 295-313.

Signs and Symptoms of Breast Disease:



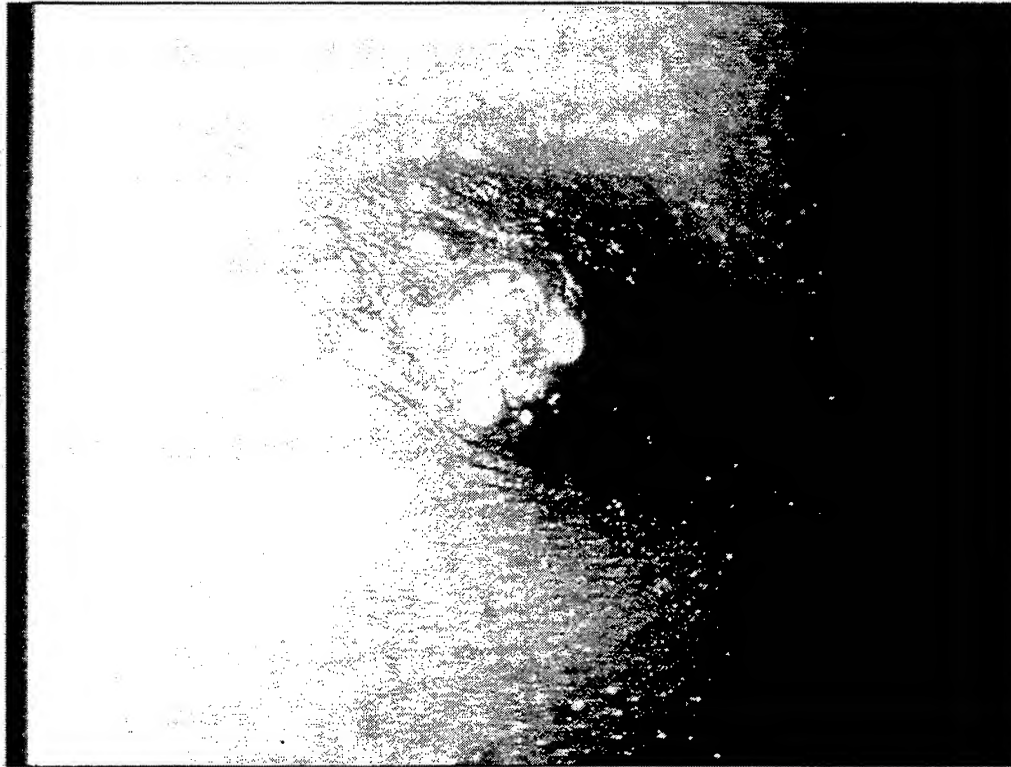
Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 171

If the discharge is bilateral, it is classified as galactorrhea versus nongalactorrhea. Both usually present as multiple duct discharge.

Source:

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.): *Textbook of Women's Health*. Philadelphia, PA: J.B. Lippincott, 1998, pp. 295-313.



Slide Credit: from Leis HP, Greene FL, Commarata A, et al. Nipple discharge: Surgical significance. *South Med J* 1988; 81:20-26. Used with permission.

SLIDE 172

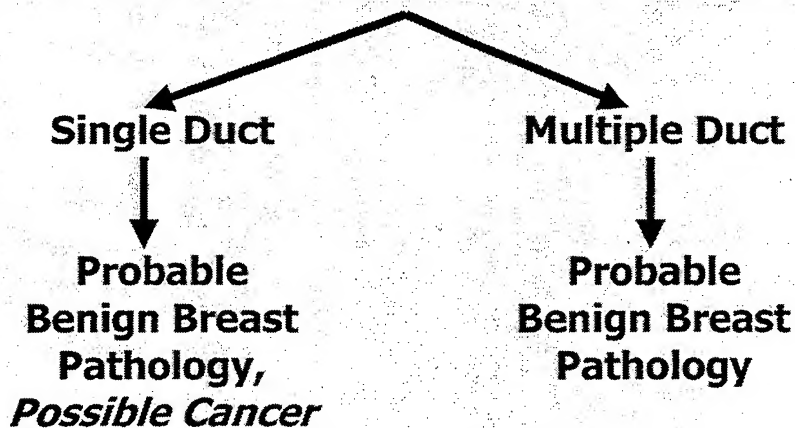
This is a typical appearance of galactorrhea. Nipple discharge of this type following cessation of lactation is very common and can continue for years as a normal phenomenon. Other etiologies include: drugs, pregnancy, presence of a pituitary adenoma, or other endocrine event. All of these conditions will be associated with an elevated prolactin level.

Source:

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.): *Textbook of Women's Health*. Philadelphia, PA: J.B. Lippincott, 1998, pp. 295-313.

Signs and Symptoms of Breast Disease:

NIPPLE DISCHARGE



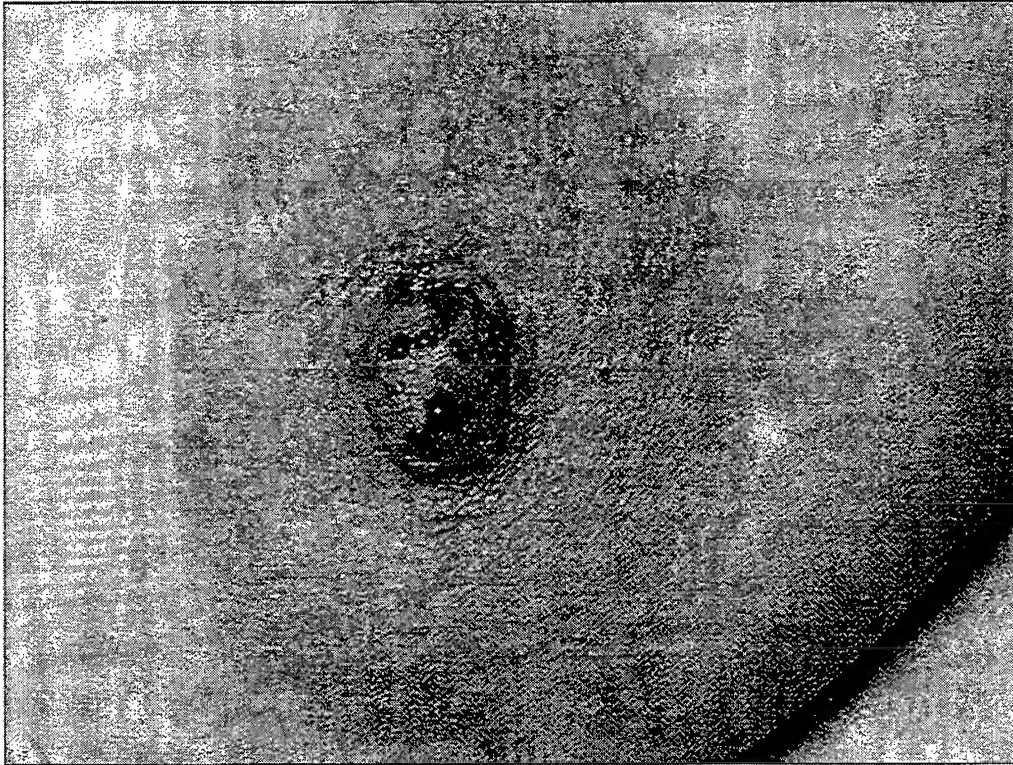
Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 173

Nipple discharge can originate from single or multiple ducts. Single-duct discharge indicates probable benign breast pathology, but also may represent cancer. Multiple-duct discharge is very unlikely to represent malignancy, particularly if it is bilateral. If the discharge is non-milky, duct ectasia is the most common diagnosis.

Source:

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.): *Textbook of Women's Health*. Philadelphia, PA: J.B. Lippincott, 1998, pp. 295-313.



Slide Credit: from Mansel RE, Runder NJ (Eds.), *Color Atlas of Breast Diseases*, Chapter 3, figure 3-8. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 174

This is an example of duct ectasia. The discharge is usually of a yellowish-green or dark green character. This condition represents a dilatation of the subareolar ducts with accumulation of stagnant secretions which cause an obstruction and subsequent discharge. These symptoms are usually followed, with surgical intervention deferred unless they cause social embarrassment. If surgery is indicated, removal of the subareolar duct system is necessary. This results in inability of the woman to lactate.

Source:

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.): *Textbook of Women's Health*. Philadelphia, PA: J.B. Lippincott, 1998, pp. 295-313.

Signs and Symptoms of Breast Disorders:

Unilateral Single-Duct Nipple Discharge

Bloody, Serous, Watery

- Will not resolve spontaneously
- Surgical intervention required

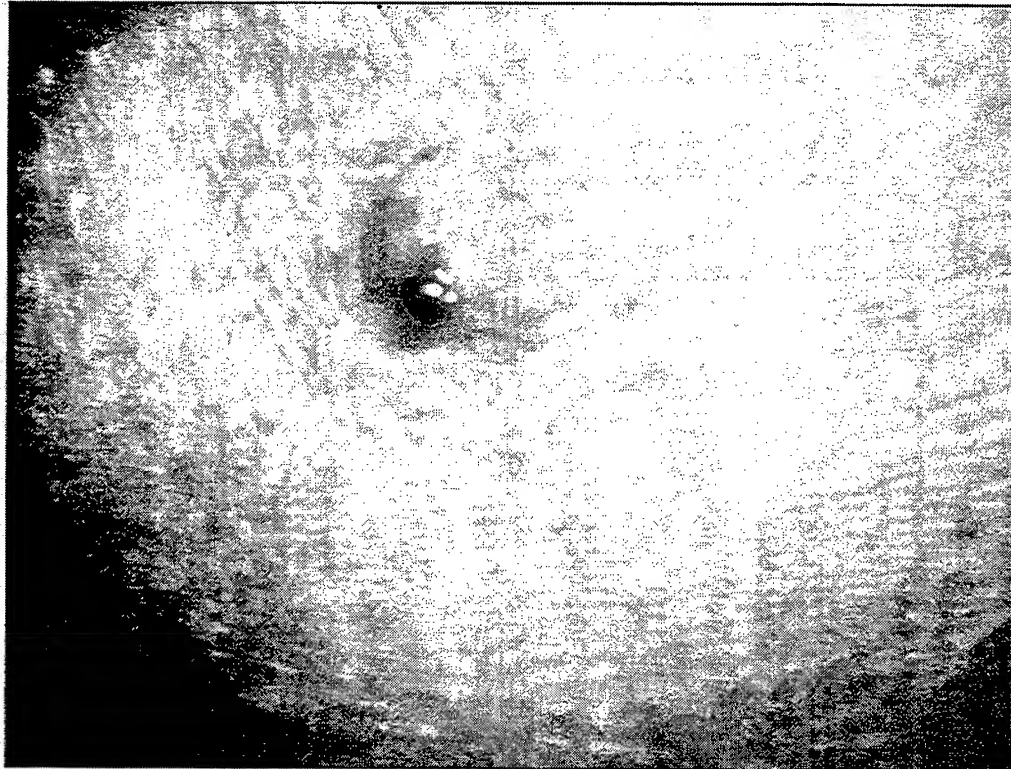
Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 175

Nipple discharge that is spontaneous, unilateral, persistent, and from a single duct is an indication for referral. The symptom is unlikely to resolve without surgical intervention, and the differential diagnosis includes carcinoma. This is true whether the character of the discharge is bloody, watery or serous.

Source:

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.): *Textbook of Women's Health*. Philadelphia, PA: J.B. Lippincott, 1998, pp. 295-313.



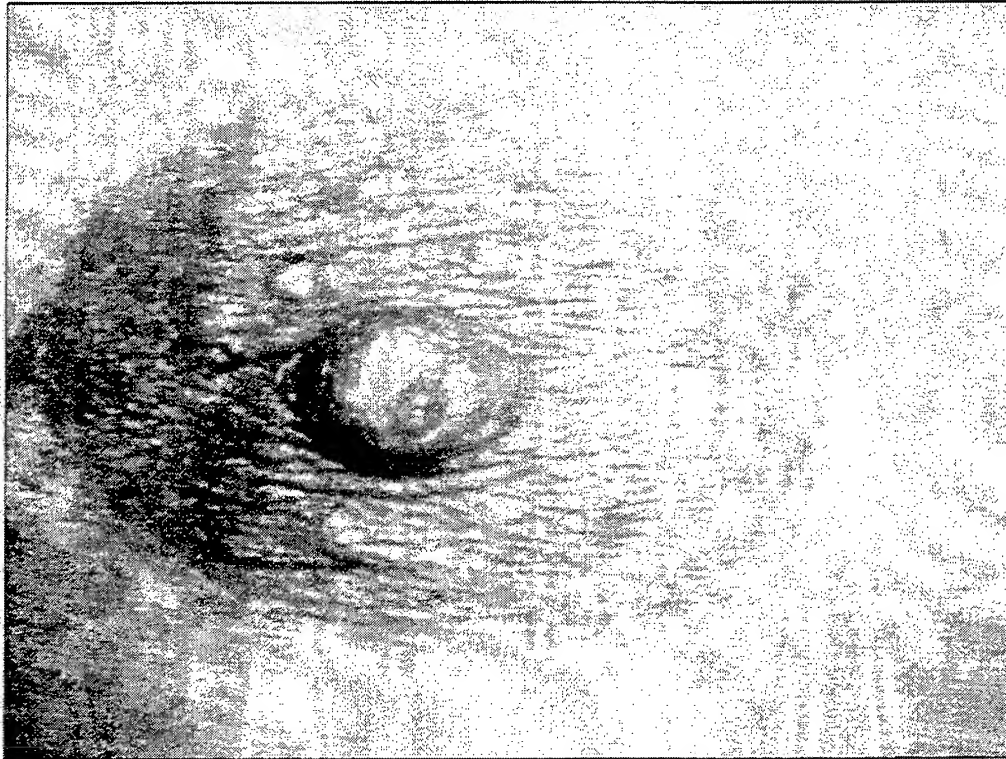
Slide Credit: from Leis HP, Greene FL, Commarata A, et al. Nipple discharge: Surgical significance. *South Med J* 1988; 81:20-26. Used with permission.

SLIDE 176

Much attention has been paid to the symptom of bloody nipple discharge. The differential diagnosis includes intraductal papilloma, duct ectasia, and carcinoma. Seventy-five to eighty-five percent of cases represent a benign intraductal papilloma.

Source:

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.): *Textbook of Women's Health*. Philadelphia, PA: J.B. Lippincott, 1998, pp. 295-313.



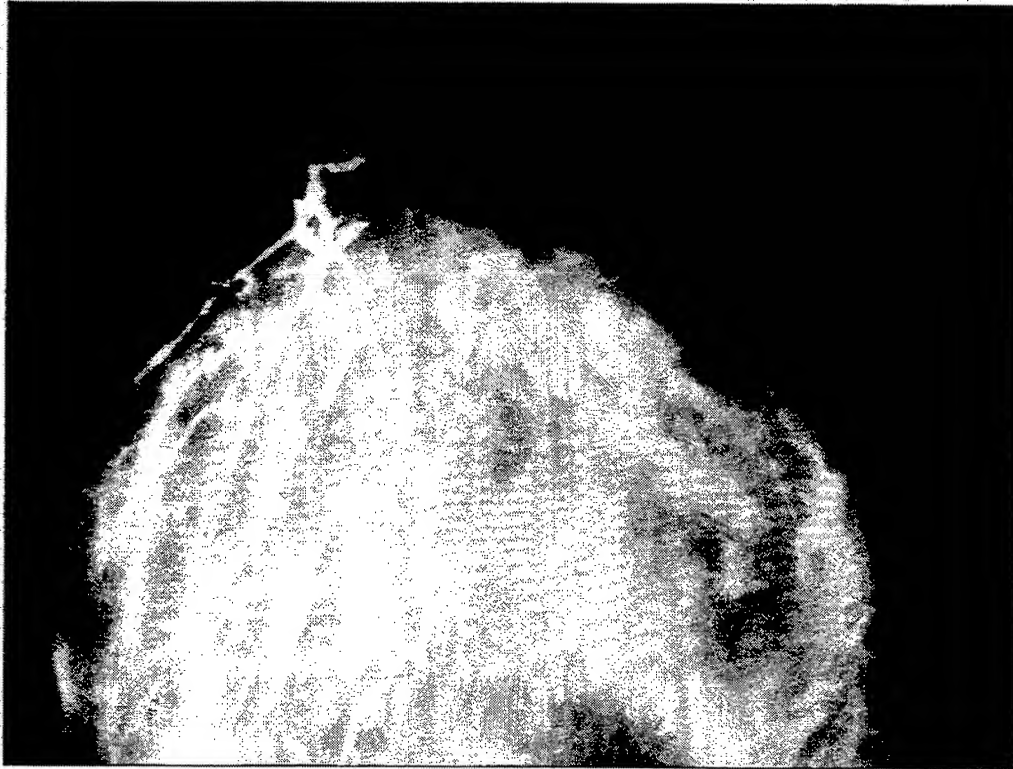
Slide Credit: from Leis HP, Greene FL, Commarata A, et al. Nipple discharge: Surgical significance. *South Med J* 1988; 81:20-26. Used with permission.

SLIDE 177

Any type of unilateral single-duct discharge is important, however. This slide demonstrates serous discharge. The differential diagnosis includes all of the conditions associated with bloody nipple discharge. Watery discharge, although uncommon, has the highest incidence of carcinoma.

Source:

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.): *Textbook of Women's Health*. Philadelphia, PA: J.B. Lippincott, 1998. pp. 295-313.



Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.
(Slide from personal collection of Janet Rose Osuch M.D., M.S.)

SLIDE 178

The work-up of the nipple discharge historically has included radiographic and laborative assessment and is uncomplicated. Mammography can be performed in age-eligible women, but is normal in most cases. Cytology of nipple discharge secretions has high false-positive and false-negative rates and is not recommended.

This is an example of a normal galactogram. This test involves the injection of radiocontrast material into the involved duct to demonstrate a filling defect on mammography. Galactography is helpful under some circumstances, especially when used for surgical localization. Galactography cannot differentiate benign from malignant duct lesions, and is generally not advocated. Surgical referral is necessary when a woman has unilateral, persistent single-duct nipple discharge.

Source:

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.): *Textbook of Women's Health*. Philadelphia, PA: J.B. Lippincott, 1998, pp. 295-313.

Signs and Symptoms of Breast Disease:

Single-Duct Nipple Discharge

ETIOLOGY

FREQUENCY

- | | |
|-------------------------|--------|
| ▪ Intraductal papilloma | 35-48% |
| ▪ Duct ectasia | 17-36% |
| ▪ Carcinoma | 5-21% |

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 179

The three most common causes of persistent, unilateral, single-duct nipple discharge are: intraductal papilloma, duct ectasia, and carcinoma. Five to 21% of women will have an underlying ductal cancer, depending on the age group, with older women much more likely to have cancer.

Source:

Winchester DP. Nipple Discharge. In: Harris JR, Lippman ME, Morrow M, et al (Eds.), *Diseases of the Breast*. Philadelphia, PA: Lippincott-Raven, 1996, pp 106-110.

Signs and Symptoms of Breast Disease:

Single-Duct Nipple Discharge

<u>TYPE</u>	<u>Frequency of Cancer</u>
Watery	- 45%
Bloody	- 25%
Serous	- 6%

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 180

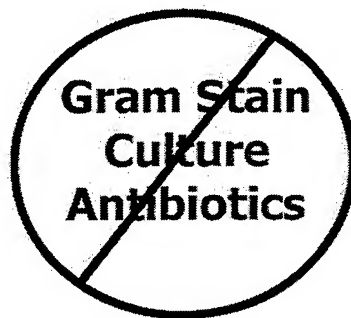
Although the most common type of single-duct nipple discharge is bloody, the etiology is malignant in only 25% of cases. Watery discharge is more likely to represent carcinoma, and is seen in 45% of women with this presentation. Only 6% of women who present with serous, single-duct nipple discharge will have cancer. Spontaneous nipple discharge is very unlikely to resolve without intervention. Diagnosis and treatment are one and the same - surgical excision. This is accomplished by passing a probe into the involved duct, raising a nipple-areolar flap, and removing the duct containing the probe. Lactation remains possible, and complications are minimal following this procedure.

Source:

Winchester DP. Nipple Discharge. In: Harris JR, Lippman ME, Morrow M, et al (Eds.), *Diseases of the Breast*. Philadelphia, PA: Lippincott-Raven, 1996, pp 106-110.

Signs and Symptoms of **Breast Disease:**

Nipple Discharge: **Other Considerations**



Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 181

The etiology of nipple discharge is not infectious in nature. A culture will usually produce staph or strep from the surface of the nipple. Administration of antibiotics is not indicated.

An algorithm summarizing the work up of nipple discharge can be found in Appendix 6.

Source:

Morris LL, Osuch JR. *Breast Cancer Education for DoD Primary Care Managers*. American Medical Women's Association, Alexandria, VA, 1997.

Signs and Symptoms of Breast Disease:

Observational Findings

- 1. Congenital**
- 2. Nipple changes**
 - **Scaling**
 - **Retraction**
- 3. Skin changes**
 - **Erythema**
 - **Dimpling**
 - **Retraction**
 - **Peau d'orange**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 182

Clinical findings that may be detected on inspection including: congenital abnormalities, nipple scaling, nipple retraction, erythema, skin dimpling, retraction, and Peau d'orange.

When inquiring about these symptoms, establish the location, the date the patient first noticed the symptoms, and whether there have been any changes since the date of symptom onset.

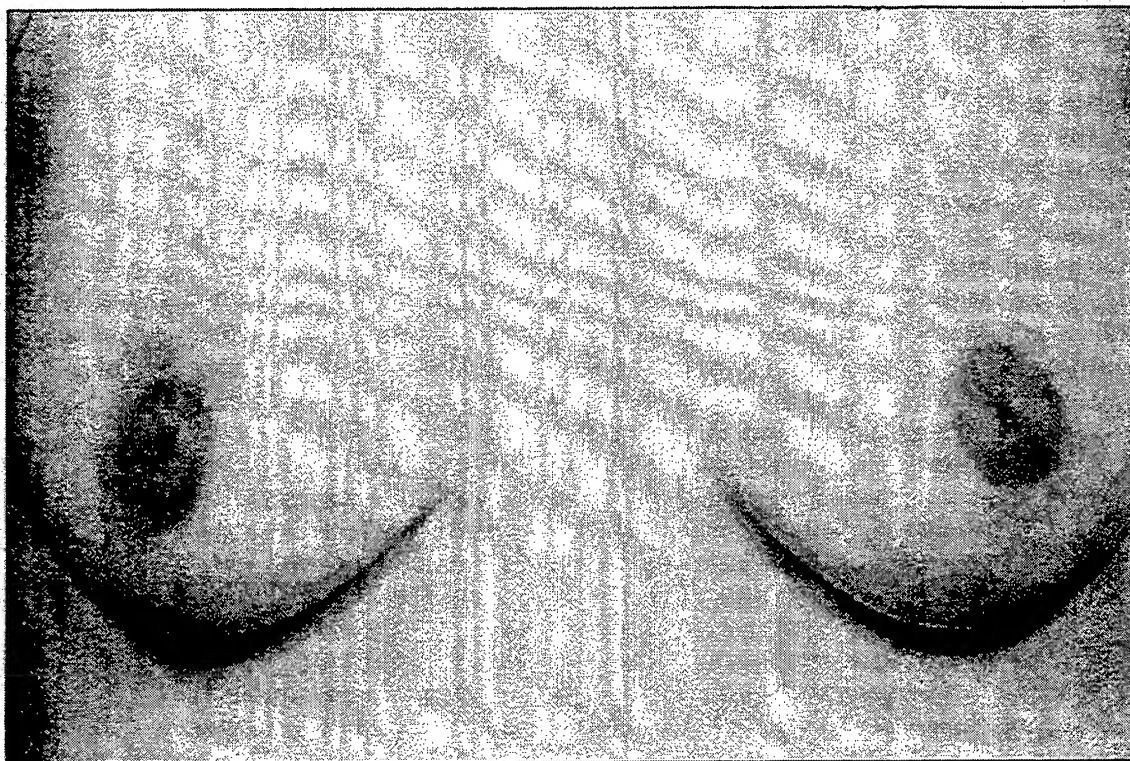
Congenital Abnormalities on CBE

- **Developmental nipple inversion**
- **Hypomastia**
- **Poland's Syndrome**
- **Supernumerary breast/nipples**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 183

Congenital abnormalities include developmental nipple inversion, hypomastia, Poland's syndrome, and supernumerary breasts or nipples.



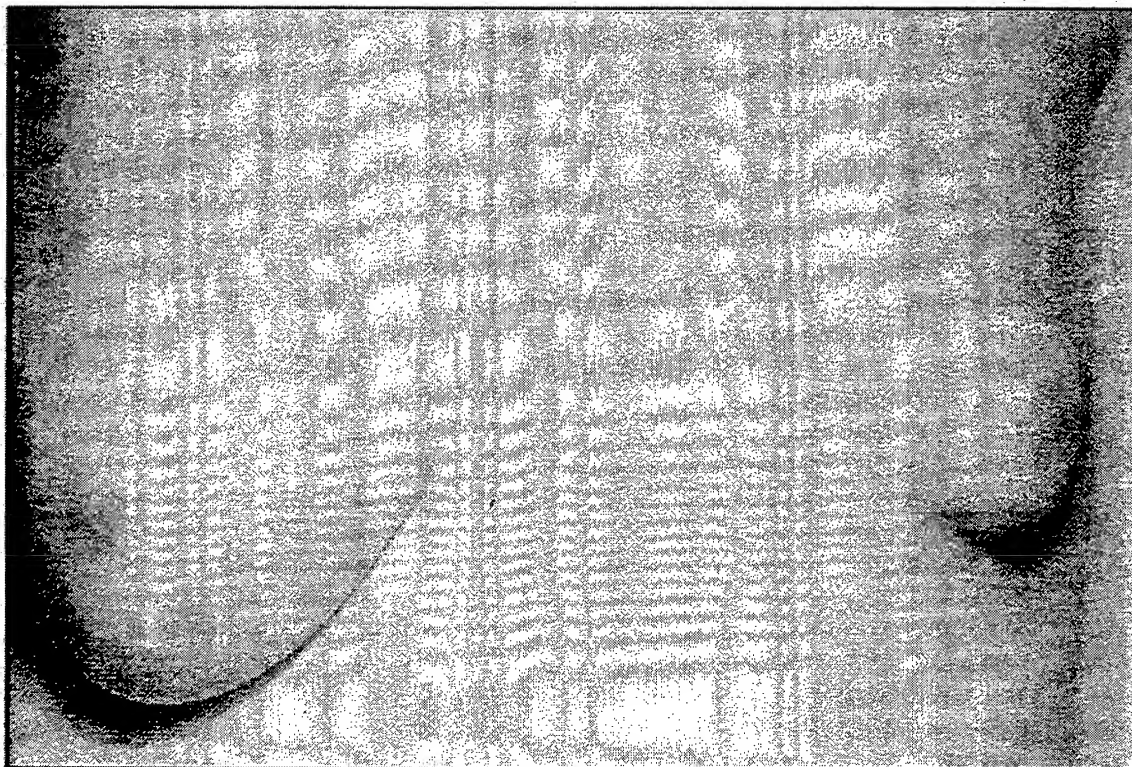
Slide Credit: from Mansel RE, Rundred NJ (Eds.), *Color Atlas of Breast Diseases*, Chapter 3, figure 3-4. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 184

This is an example of inversion of the nipple. If the patient's history confirmed that this finding was present since adolescence, the abnormality is developmental. The nipples evert as one of the last steps in breast development, occurring at about age 12. The presence of nipple inversion predisposes to subareolar abscess. If a patient indicates that the nipple has been inverting slowly over time from a previously everted state, the differential diagnosis includes periductal mastitis vs subareolar carcinoma. This will be discussed in more detail later.

Source:

The duct ectasia /periductal mastitis complex. In: Hughes LE, Mansel RE, Webster DJT (Eds.) *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management*. London: Baillière Tindall, 1989, pp. 107-131.



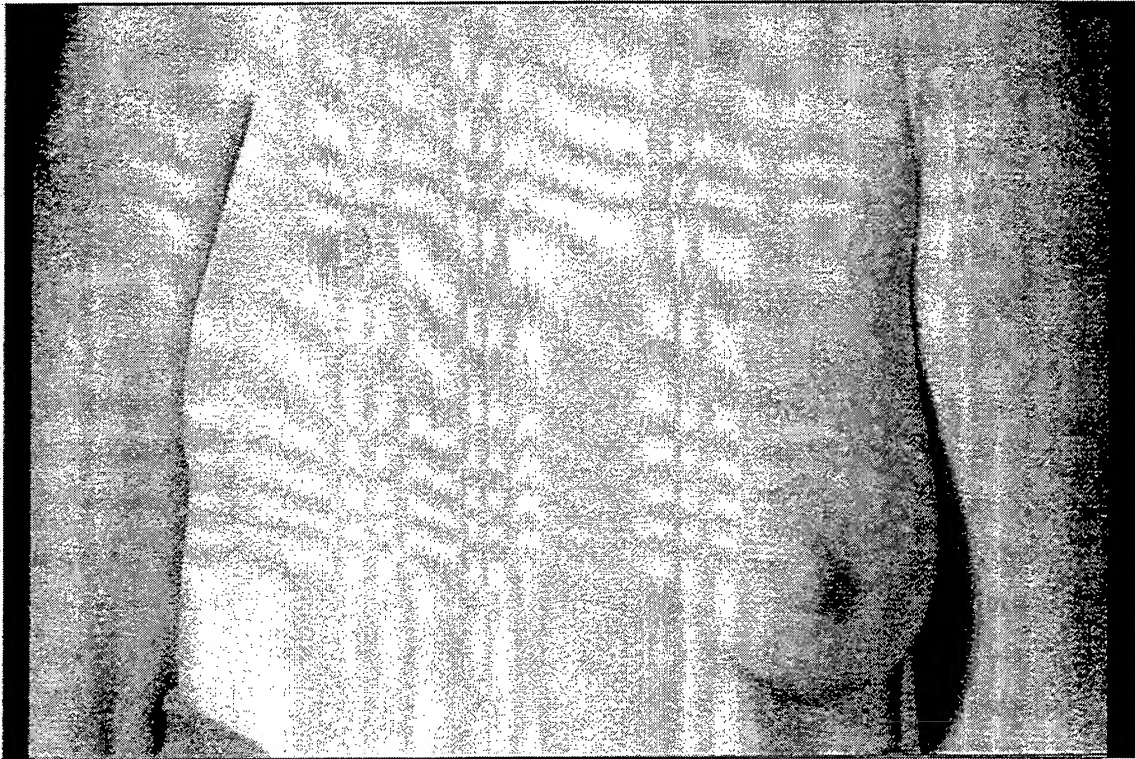
Slide Credit: from Mansel RE, Rundred NJ (Eds.). *Color Atlas of Breast Diseases*. Chapter 1, figure 1-16. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 185

This is an example of breast hypoplasia. Correction of a visible asymmetry such as this would require plastic surgery. Hypomastia can be congenital or acquired. If the latter, it is usually iatrogenic, from ill-placed chest tubes in the neonatal period, chest wall radiation therapy prior to pubescence, or inappropriate surgical resection of the breast bud.

Source:

The duct ectasia /periductal mastitis complex. In: Hughes LE, Mansel RE, Webster DJT (Eds.) *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management*. London: Baillière Tindall, 1989, pp. 107-131.



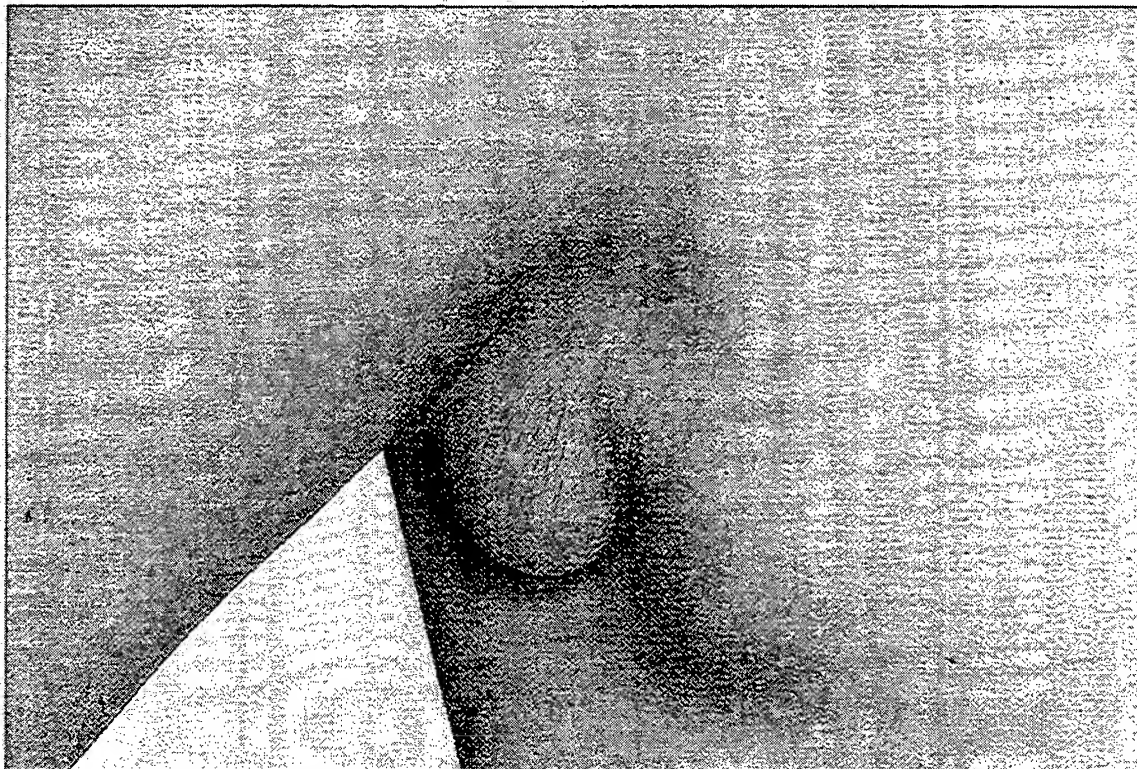
Slide Credit: from Mansel RE, Rundred NJ (Eds.). *Color Atlas of Breast Diseases*. Chapter 1, figure 1-15. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 186

Poland's syndrome represents hypomastia of one breast, with absence of the pectoralis major muscle. This is not common. Cosmetic symmetry should be accomplished by plastic surgery.

Source:

Normal breast. In: Mansel RE, Bundred NJ (Eds.). *Color Atlas of Breast Diseases*. London: Mosby-Wolfe, 1995, pp. 7-20.



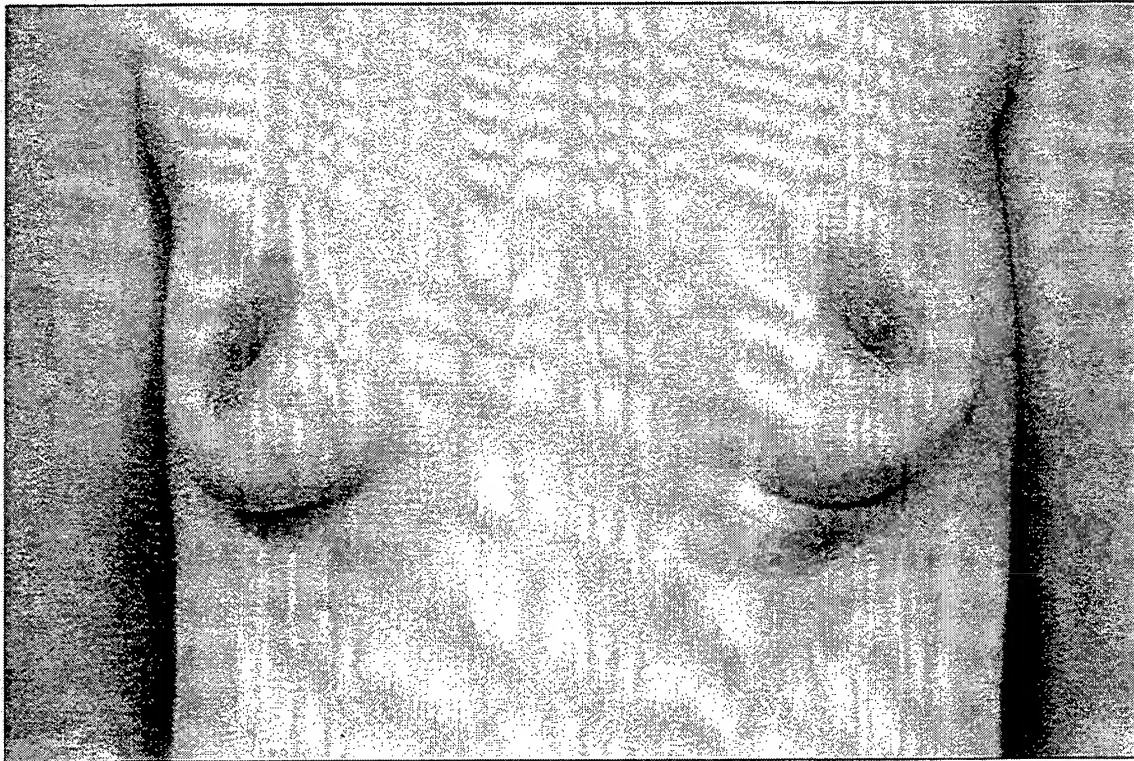
Slide Credit: from Mansel RE, Rundred NJ (Eds.), *Color Atlas of Breast Diseases*, Chapter 1, figure 1-14. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 187

Supernumerary or extra breasts are common, and the most frequent site of presentation is the axilla. Developmentally, all mammals have the potential to develop breasts from the axilla to the groin, along the milk line. In human beings during normal embryological development, several breasts can form, but all but two usually recede by birth. However, residual supranumerary breasts or nipples occur in about 10% of the population, and because the condition is inherited as an autosomal dominant characteristic, it occurs in women and in men with equal frequency. Because the tissue is hormonally responsive, it can become engorged and painful during pregnancy and in cycling in women. If symptoms mandate, surgical excision is indicated.

Source:

The duct ectasia/periductal mastitis complex. In: Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management*. London: Baillière Tindall, 1989, pp. 159-166.



Slide Credit: from Mansel RE, Rundred NJ (Eds.), *Color Atlas of Breast Diseases*, Chapter 1, figure 1-12. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 188

Polythelia, or extra nipples are also common, either associated with supernumerary breasts or occurring separately. This slide demonstrates both. On the right is a supernumerary breast and nipple complex. Some women can lactate from this structure. On the left is a supernumerary nipple. It most often occurs in an inframammary location, and is often mistaken for a skin tag or mole.

Source:

The duct ectasia /periductal mastitis complex. In: Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management*. London: Baillière Tindall. 1989, pp. 159-166.



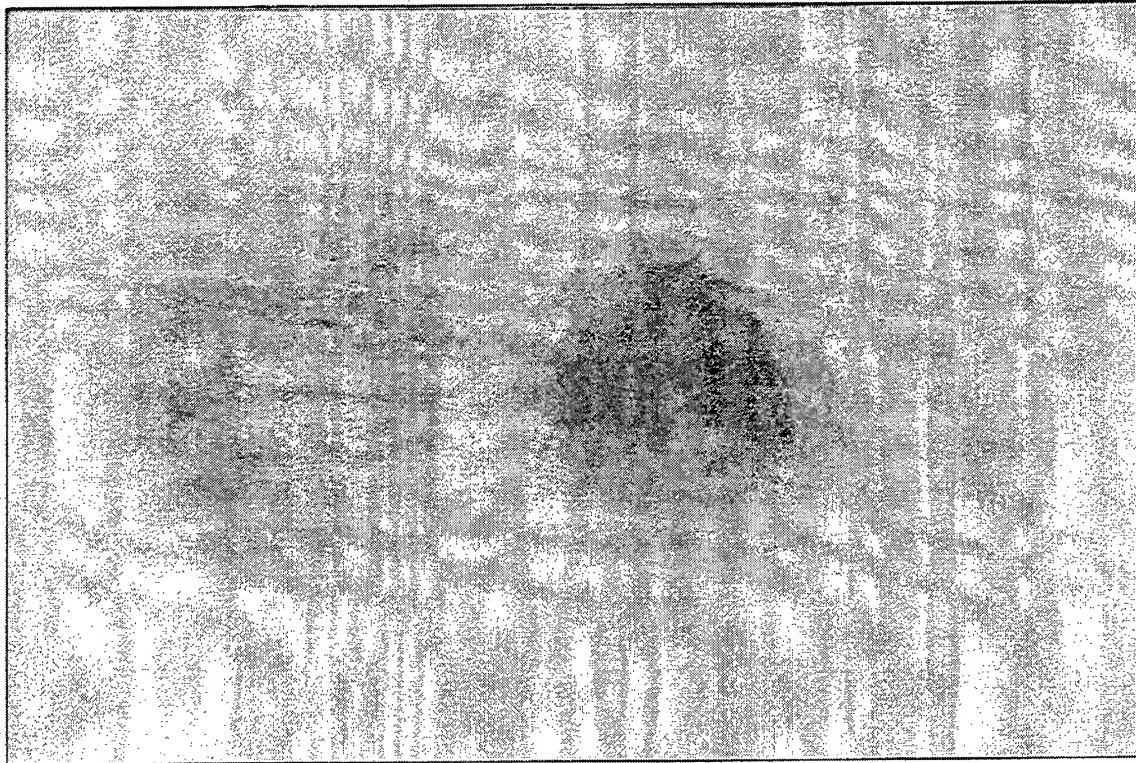
Slide Credit: from Mansel RE, Runder NJ (Eds.), *Color Atlas of Breast Diseases*, Chapter 1, figure 1-5. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 189

This is the normal appearance of the nipple-areolar complex. Montgomery glands are visible as bumps around the areola. These become more prominent during pregnancy.

Source:

Normal breast. In: Mansel RE, Bundred NJ (Eds.). *Color Atlas of Breast Diseases*. London: Mosby-Wolfe, 1995.



Slide Credit: from Mansel RE, Rundred NJ (Eds.), *Color Atlas of Breast Diseases*. Chapter 3, figure 3-14. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 190

This slide demonstrates the appearance of eczema of the areola, which presents as pruritis and skin scaling. Notice that the nipple is not involved with the scaly hyperpigmented process present medially in this patient's breast. Eczema rapidly responds to local hydrocortisone cream therapy.

Source:

Disorders of the Nipple and Areola. In: Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management*. London: Baillière Tindall, 1989. pp. 151-157.



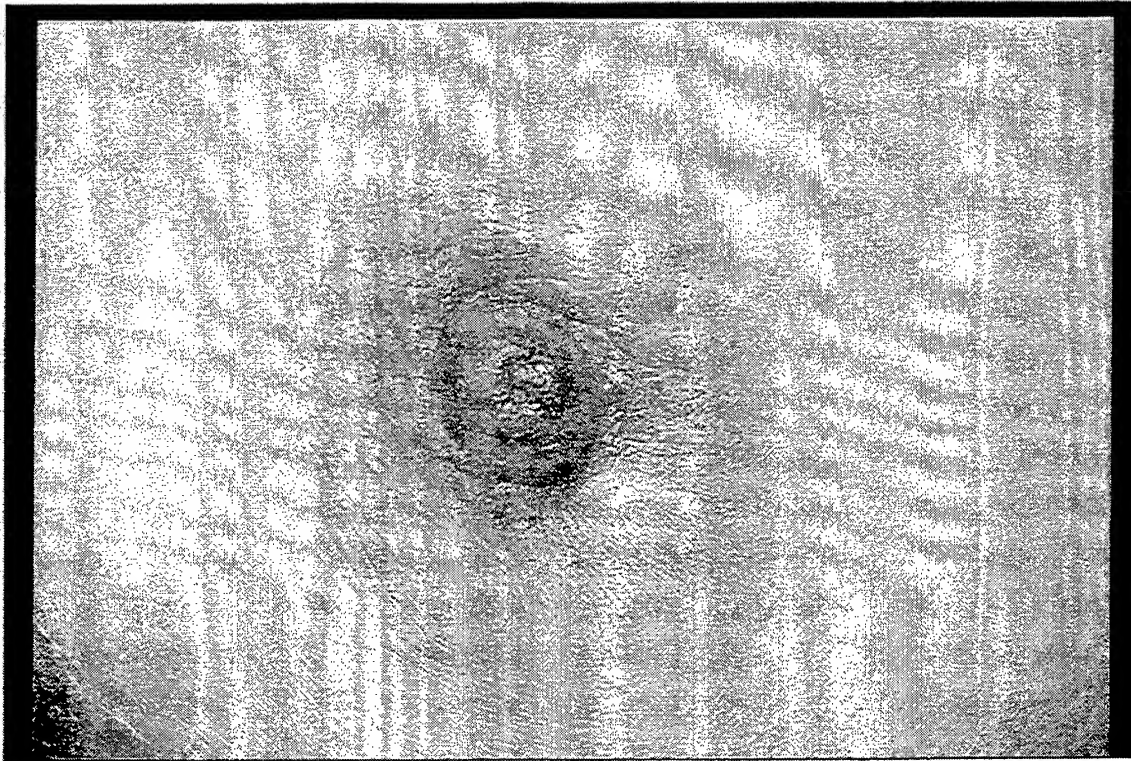
Slide Credit: from Mansel RE, Runderd NJ (Eds.), *Color Atlas of Breast Diseases*. Chapter 3, figure 3-15. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 191

This is an example of a more advanced case of areolar eczema. Sometimes the process can involve the nipple, but this is uncommon.

Source:

The duct ectasia /periductal mastitis complex. In: Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management*. London: Baillière Tindall, 1989, pp. 151-157.



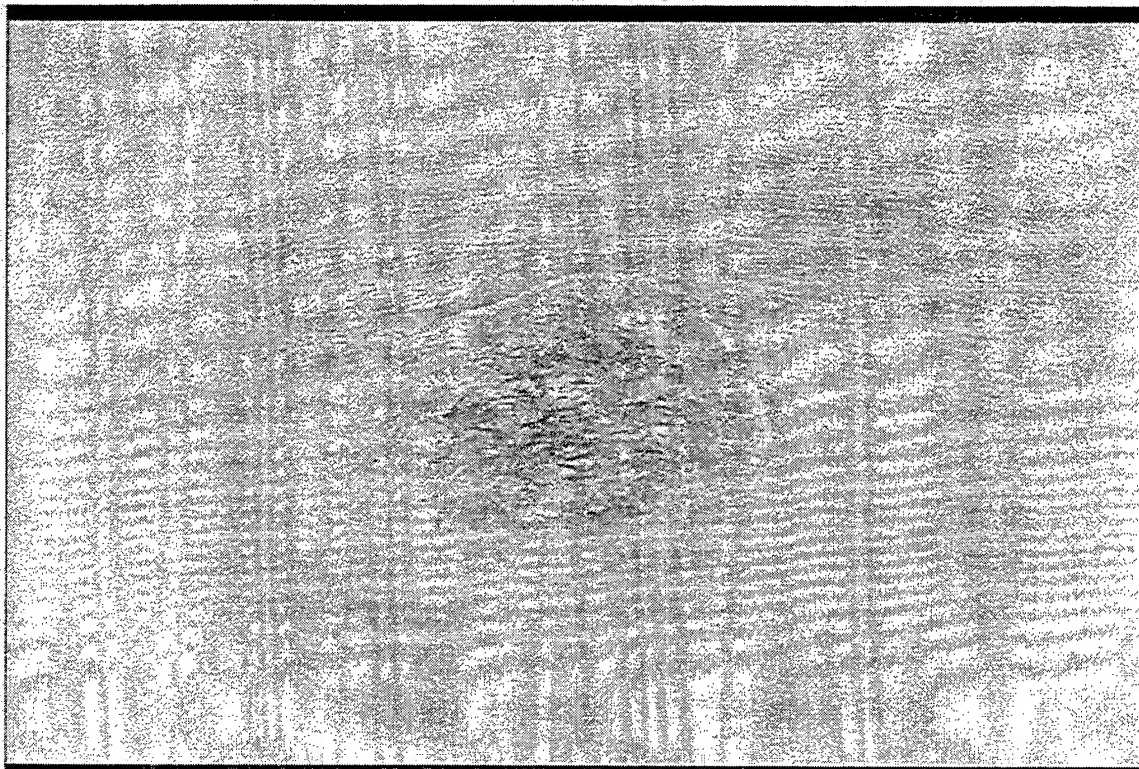
Slide Credit: from Mansel RE, Rundred NJ (Eds.), *Color Atlas of Breast Diseases*, Chapter 3, figure 3-18. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 192

This slide demonstrates the appearance of early Paget's disease. Paget's disease represents cancer of the subareolar ducts and often is associated with no other findings on CBE or mammography. If the areola is involved in an eczematous process and the nipple is not, Paget's disease should not be part of the differential diagnosis. To differentiate between the two processes when uncertain, keep in mind that Paget's disease may respond to, but will not resolve with topical steroid creams. Misdiagnosis of Paget's disease is one cause of delayed diagnosis of breast cancer. Any patient who does not respond to topical treatment with hydrocortisone within 2 weeks of initiation needs a surgical referral.

Source:

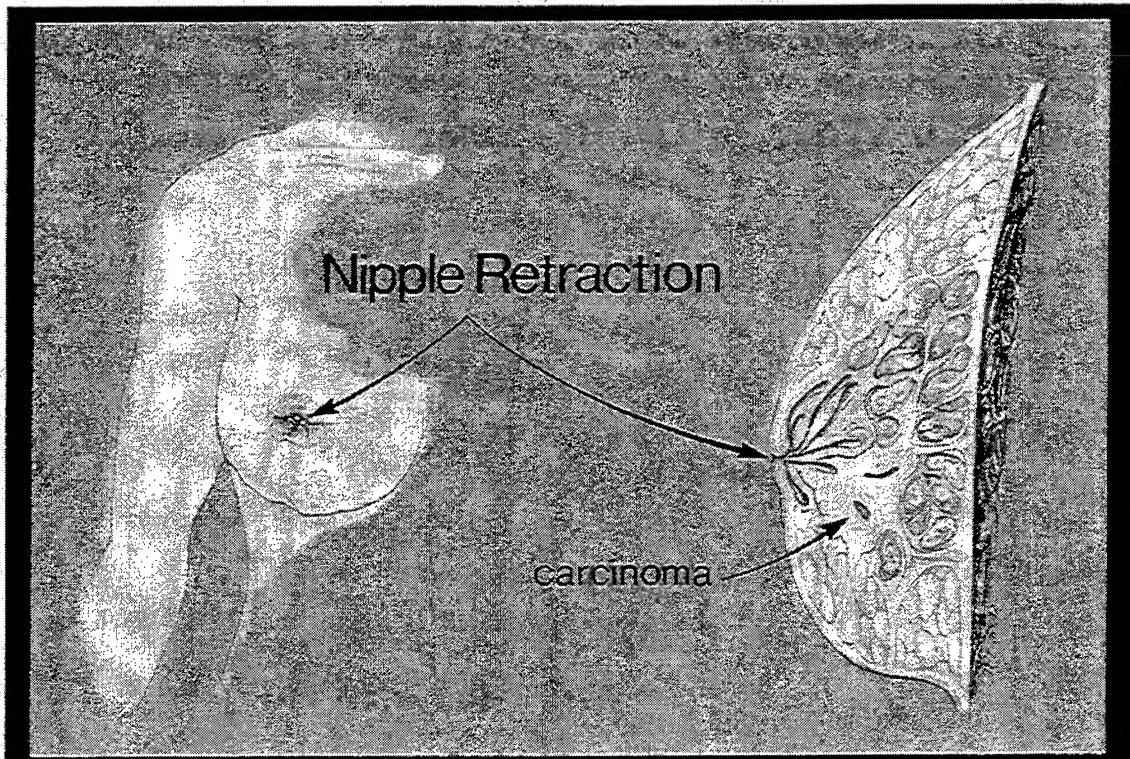
Disorders of the Nipple and Areola. In: Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management*. London: Baillière Tindall, 1989, pp. 151-157.



Slide Credit: from Mansel RE, Rundred NJ (Eds.), *Color Atlas of Breast Diseases*, Chapter 3, figure 3-19. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 193

Paget's disease, as it advances, destroys the nipple. Even in this case, no underlying mass was palpable.



Slide Credit: Slide No. 153 from Osuch JR, Dell DL, Sleighter S. *Breast and Cervical Cancer Education for Primary Care Providers*. Alexandria, VA: American Medical Women's Association, 1994. Joyce Lavery, MFA, CMI. Used with permission.

SLIDE 194

Nipple retraction, unlike nipple inversion, is a serious condition. Nipple retraction is the gradual onset of nipple inversion and is usually associated with broadening of the nipple and flattening of the nipple-areola complex. Until proven otherwise, nipple retraction implies that there is a carcinoma in the retro-areolar part of the breast. If a patient presents with new onset of nipple retraction, it requires surgical referral.

Source:

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.), *Textbook Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.



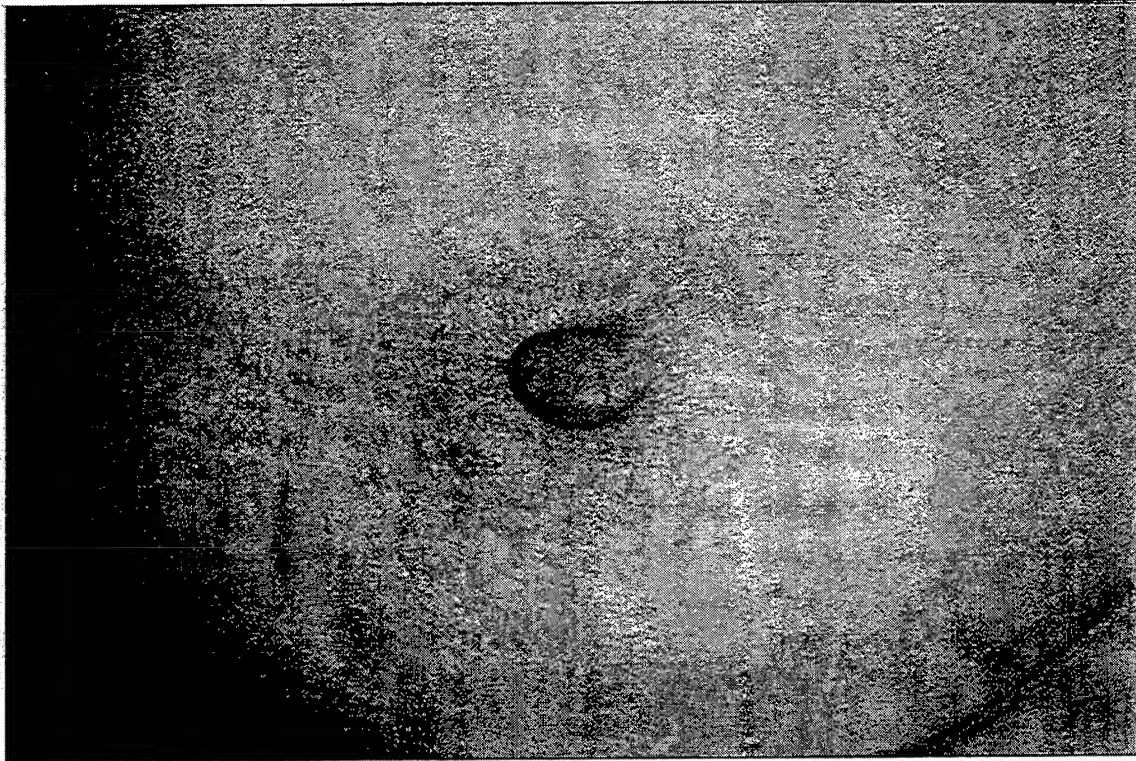
Slide Credit: from Mansel RE, Rundred NJ (Eds.), *Color Atlas of Breast Diseases*, Chapter 3, figure 3-3. London: Times Mirror International Publishers Limited, 1995: Used with permission.

SLIDE 195

This is an example of acquired nipple inversion. Although the differential diagnosis in such cases includes carcinoma, this appearance is more consistent with the sequelae of periductal mastitis which occurs in association with duct ectasia. A history consistent with the latter, the commonly bilateral nature of the condition, and the presence of an otherwise normal CBE and mammogram will help differentiate the two. Referral is appropriate when uncertainty exists.

Source:

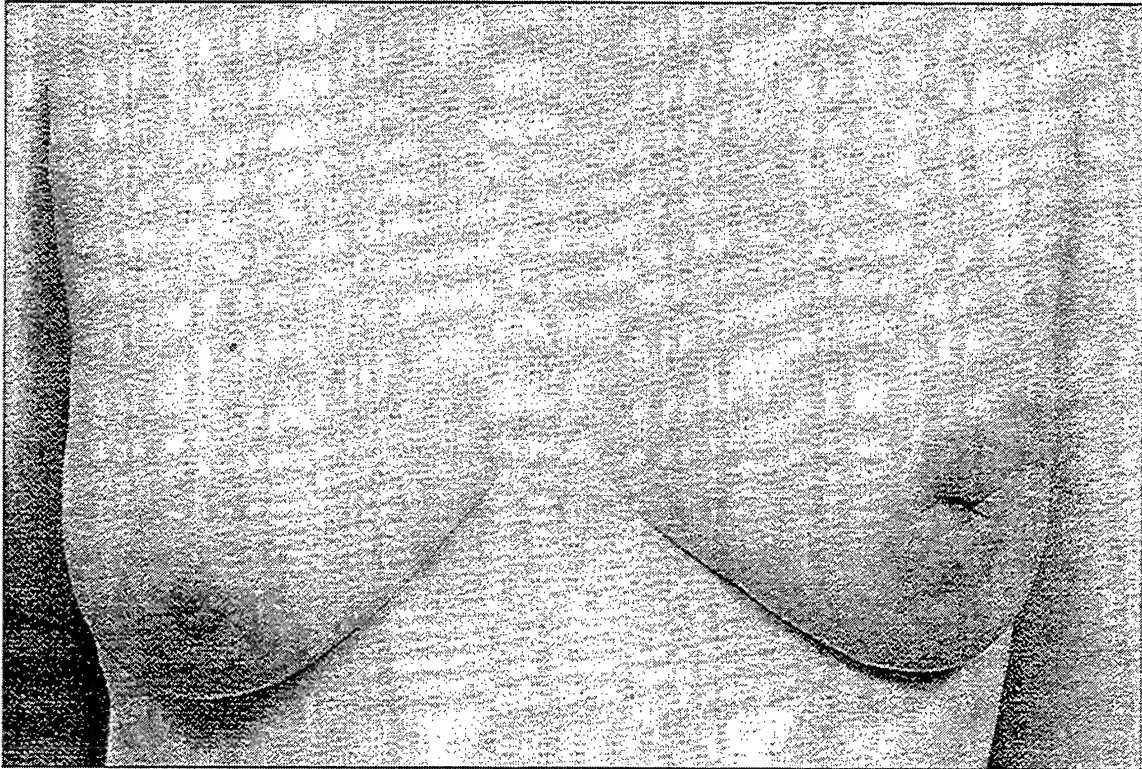
The duct ectasia/periductal mastitis complex. In: Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management*. London: Baillière Tindall, 1989, pp. 107-131.



Slide Credit: from Mansel RE, Rundred NJ (Eds.), *Color Atlas of Breast Diseases*, Chapter 2, figure 2-8. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 196

This slide illustrates the presentation of lateral retraction of the nipple. The nipple is flattened and broadened. This woman has carcinoma in the retro-areolar location in her breast. A palpable thickening is present laterally.



Slide Credit: from Mansel RE, Runderd NJ (Eds.), *Color Atlas of Breast Diseases*, Chapter 7, figure 7-6. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 197

This is a more advanced example of subareolar carcinoma, causing complete left nipple inversion.

Signs and Symptoms of Breast Disease

Observational Findings

SKIN CHANGES

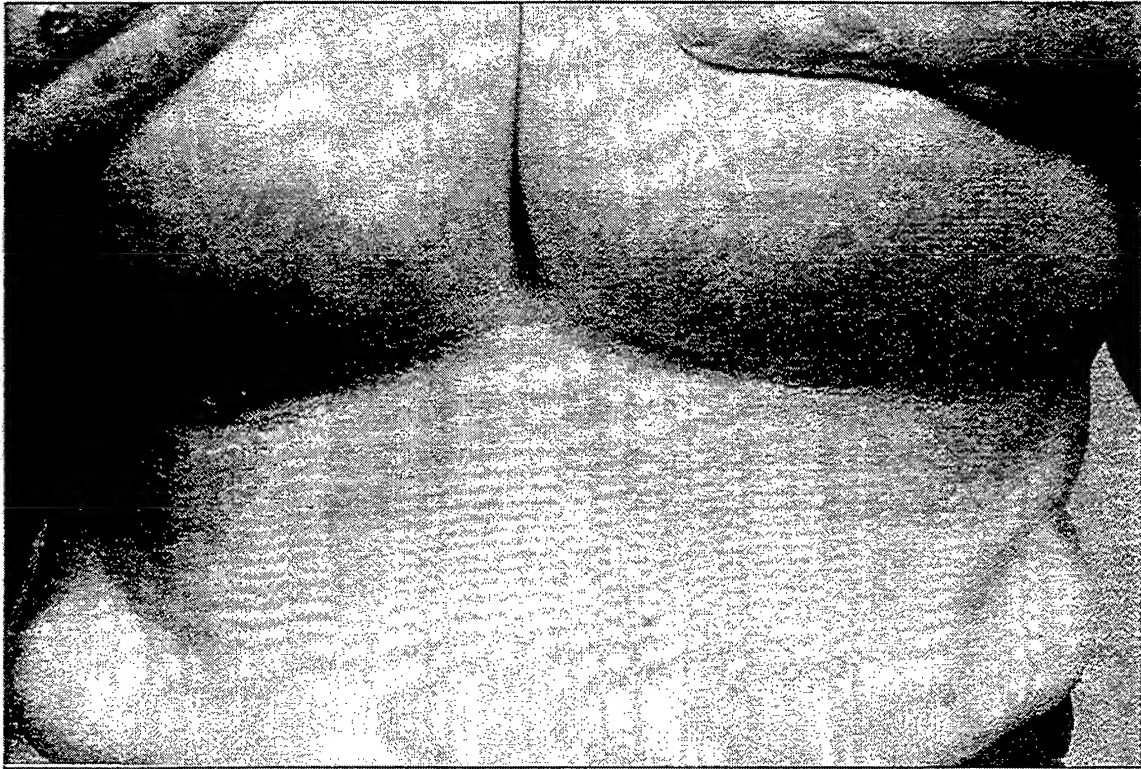
Erythema
Dimpling
Skin Retraction
Peau d'Orange

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 198

There are multiple causes for skin changes observed on CBE. Most of these have an etiology, like nipple changes, of either an inflammatory process or carcinoma.

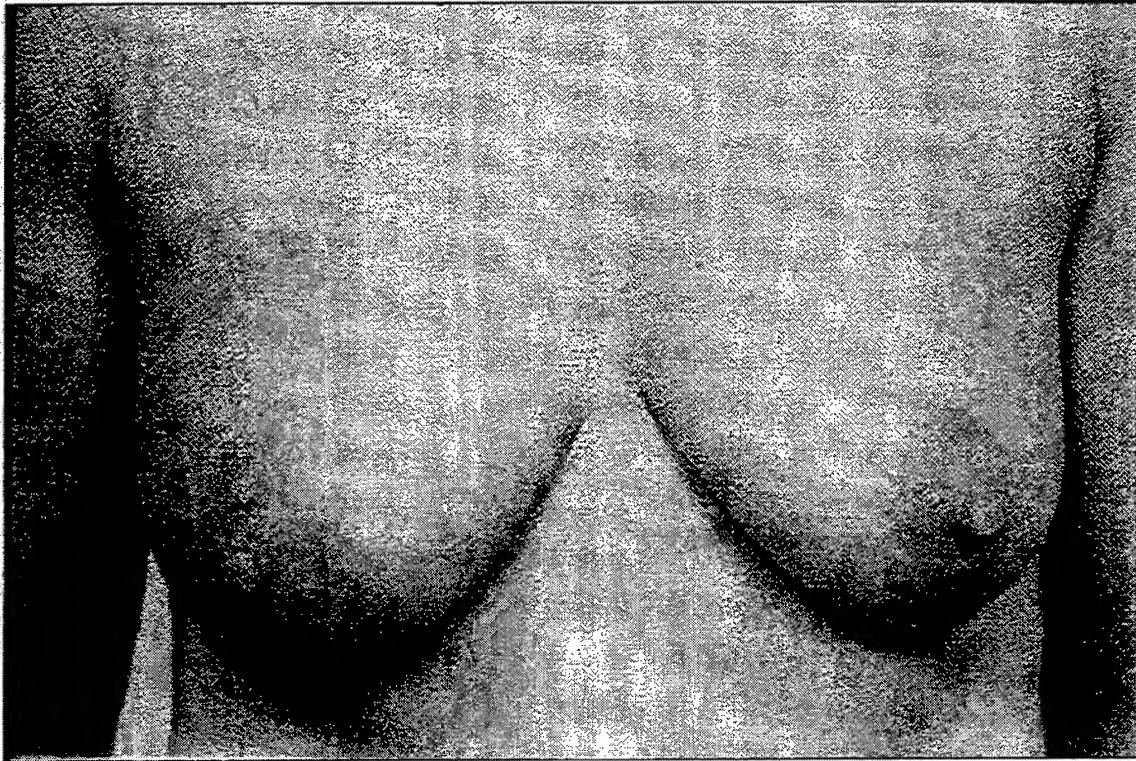
We will observe examples of each common skin change in the following slides.



Slide Credit: from Mansel RE, Rundred NJ (Eds.), *Color Atlas of Breast Diseases*, Chapter 5, figure 5-28. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 199

This is an example of intertrigo. It commonly occurs in older women in the folds of large pendulous breasts, and is not associated with carcinoma. Zinc oxide or talc to keep the area dry is helpful. The disease is of fungal origin, and can be treated with anti-fungal creams. The possibility of diabetes should be investigated in cases of intertrigo.



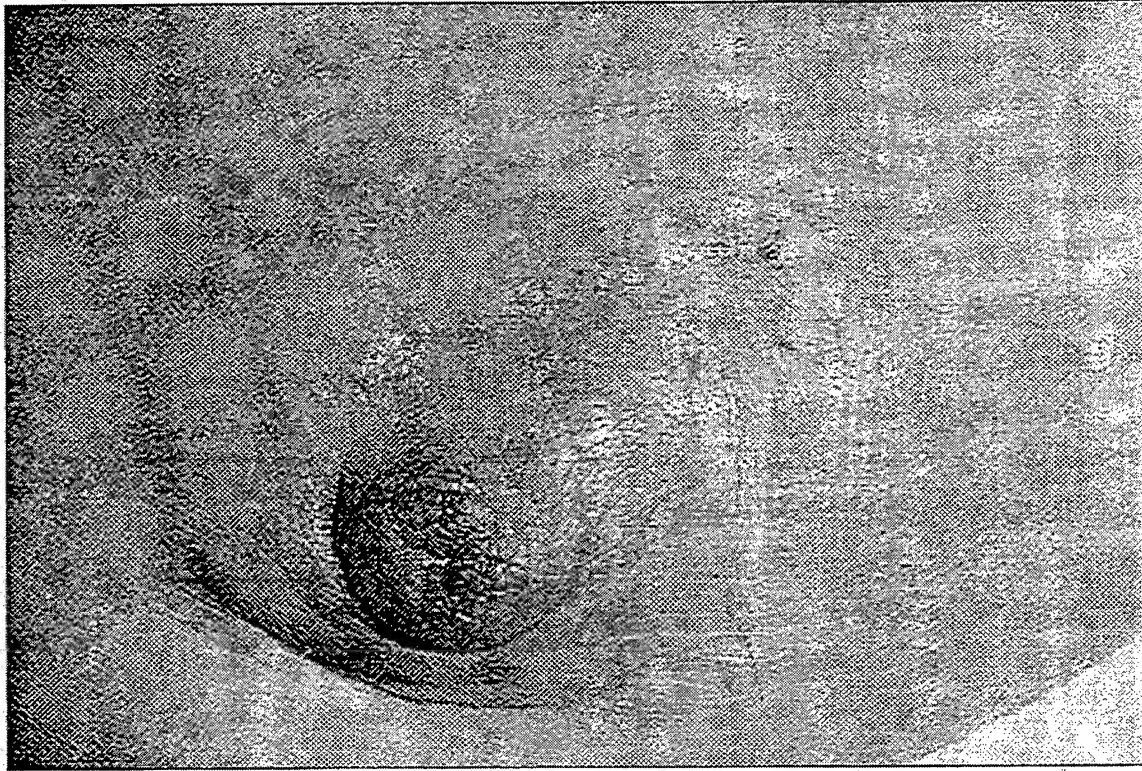
Slide Credit: from Mansel RE, Rundred NJ (Eds.), *Color Atlas of Breast Diseases*. Chapter 5, figure 5-5. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 200

This example of mastitis of the right breast could be of lactational or non-lactational origin. Lactational mastitis is treated with warm compresses and if unresolved within 24 hours, with an antibiotic active against *Staphylococcus aureus*. Early treatment of the cellulitis is important to avoid abscess formation. Complete resolution is usual and referral is unnecessary unless an abscess develops.

Source:

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.), *Textbook Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.



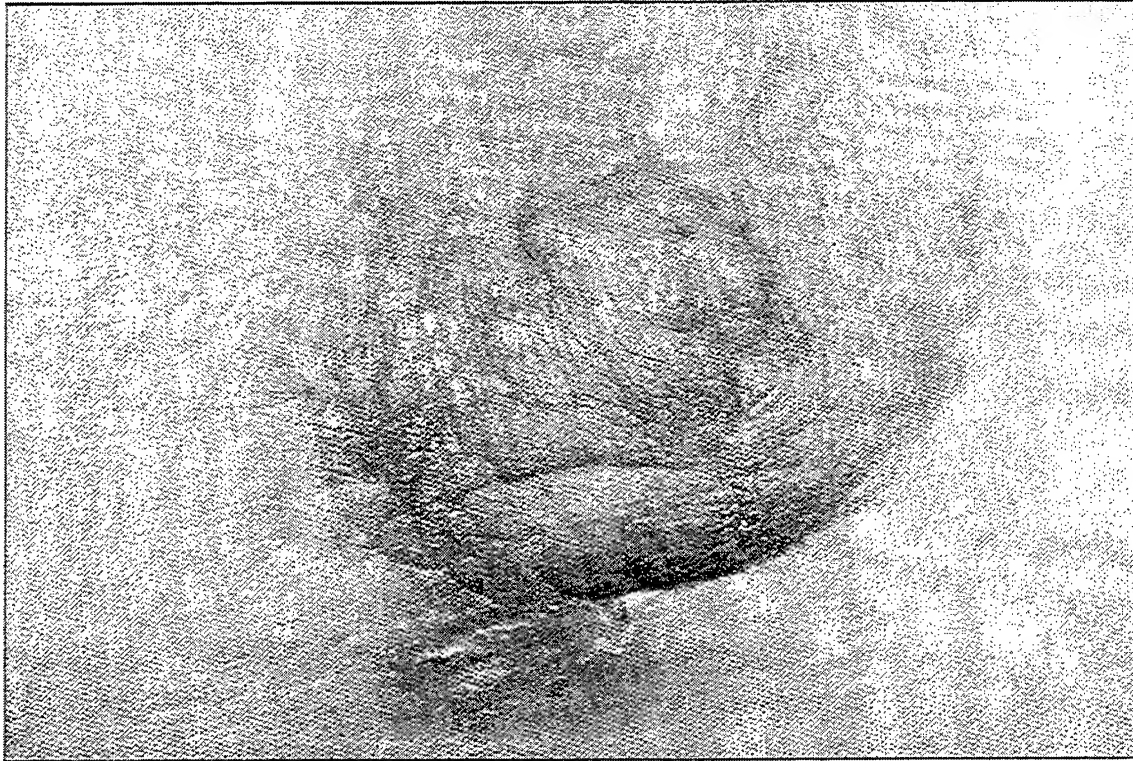
Slide Credit: from Mansel RE, Runder NJ (Eds.), *Color Atlas of Breast Diseases*. Chapter 5, figure 5-3. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 201

Periductal mastitis is secondary to duct ectasia and bacterial colonization of the subareolar ducts. It sometimes causes acute mastitis of the peri-areolar system. When it occurs, it needs to be treated with antibiotics active against Staphylococcus aureus and anaerobic organisms. If the condition progresses to abscess formation, incision and drainage followed by removal of the subareolar ductal system becomes necessary to prevent recurrence. This is a difficult condition to treat successfully, and recurrences are common, even with surgical intervention.

Source:

The duct ectasia /periductal mastitis complex. In: Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management*. London: Baillière Tindall, 1989, pp. 107-131.



Slide Credit: from Blamey R, Evans A, Ellis I, et al. (Eds.). *Atlas of Breast Cancer*. Figure 27. Hampshire, UK: Merit Publishing International, 1994. Used with permission.

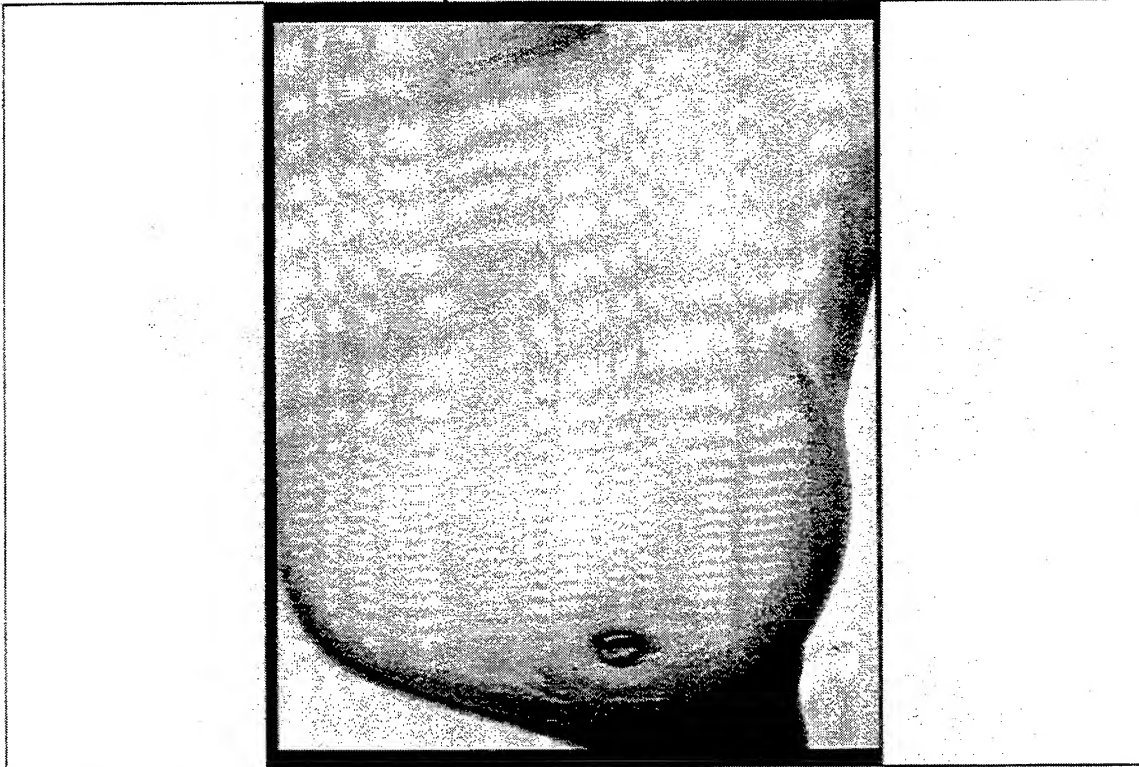
SLIDE 202

Repeated recurrences of a peri-areolar abscess secondary to periductal mastitis can result in a mammary fistula, manifested by chronic peri-areolar drainage and distortion.

Repeated incision and drainage will not resolve the problem. Instead, excision of the major ducts and fistulous tract will be necessary. This condition is much more likely to occur in smokers and smoking cessation will often be necessary to resolve the problem permanently after surgical treatment.

Source:

The duct ectasia /periductal mastitis complex. In: Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management*. London: Baillière Tindall, 1989, pp. 107-131.



Slide Credit: from Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast – Concepts and Clinical Management*, Chapter 13, figure 13.4. London: Baillier Tindall, 1989. Used with permission.

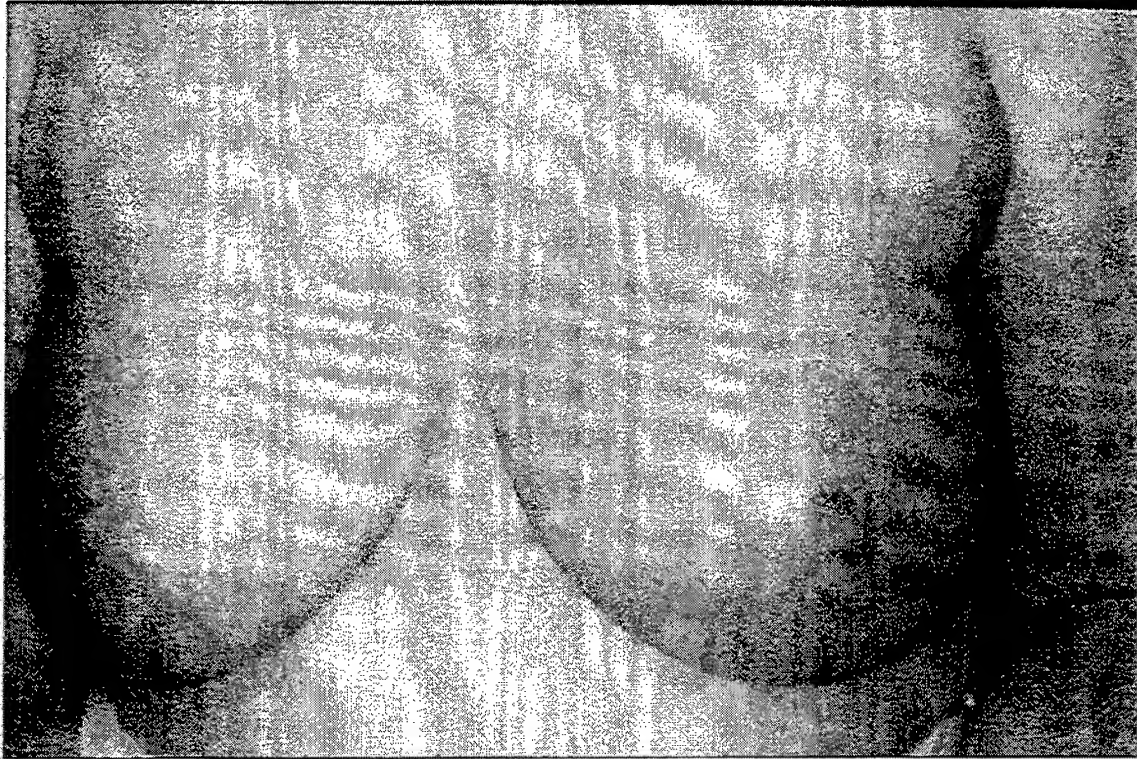
SLIDE 203

This is a case of erythema involving the entire breast and represents advanced inflammatory carcinoma. Note the nipple retraction.

Inflammatory breast cancer is an ominous condition associated with an extremely poor prognosis. Many times no mass can be palpated; mammography demonstrates skin thickening and increased density in the breast, but often no specific abnormalities.

Source:

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.). *Textbook Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.



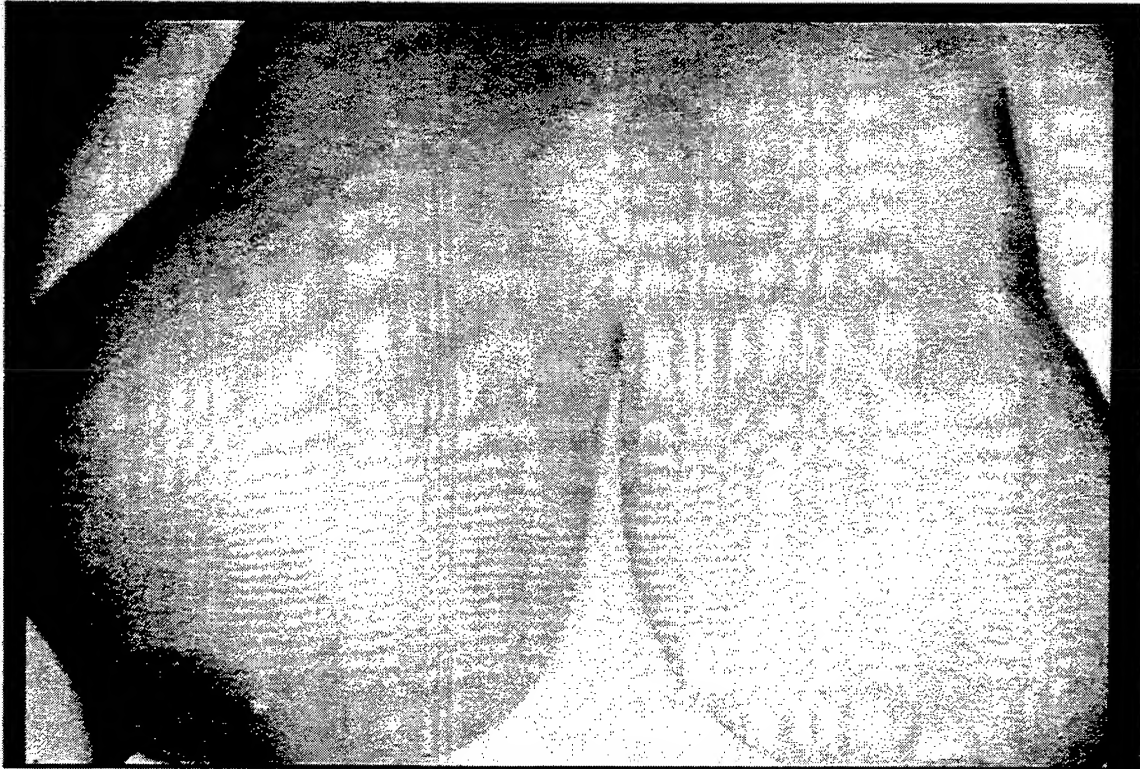
Slide Credit: from Hayes DF (Ed.). *Atlas of Breast Cancer*. Chapter 8, figure 8.16. London: Mosby Europe Ltd., 1993.

SLIDE 204

A more subtle presentation of inflammatory cancer is that of localized mastitis in a non-lactating woman. Usually pain and fever are absent, but the differential diagnosis can be challenging. Persistent mastitis beyond 2 weeks that does not resolve with antibiotics is a cause for grave concern, and an indication for surgical referral.

Source:

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.), *Textbook Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.



Slide Credit: American Cancer Society, Atlanta, GA. Public Domain.

SLIDE 205

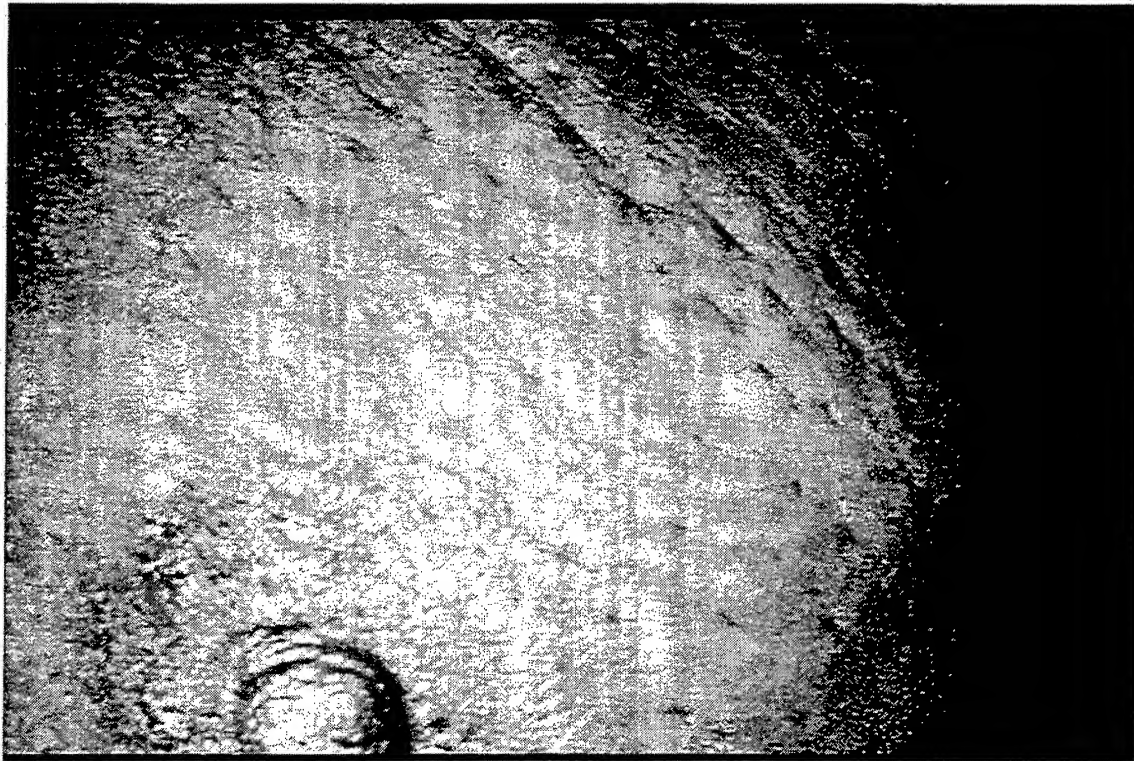
Often accompanying breast erythema is peau d'orange, a term denoting skin thickening.

This implies obstruction of the dermal lymphatics with inflammatory or malignant cells.

Symptoms of erythema and peau d'orange that do not respond to antibiotic therapy within 2 weeks need referral to rule out inflammatory carcinoma.

Source:

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.), *Textbook Women's Health*. Philadelphia, PA: Lippincott-Raven. 1998, pp. 295-313.



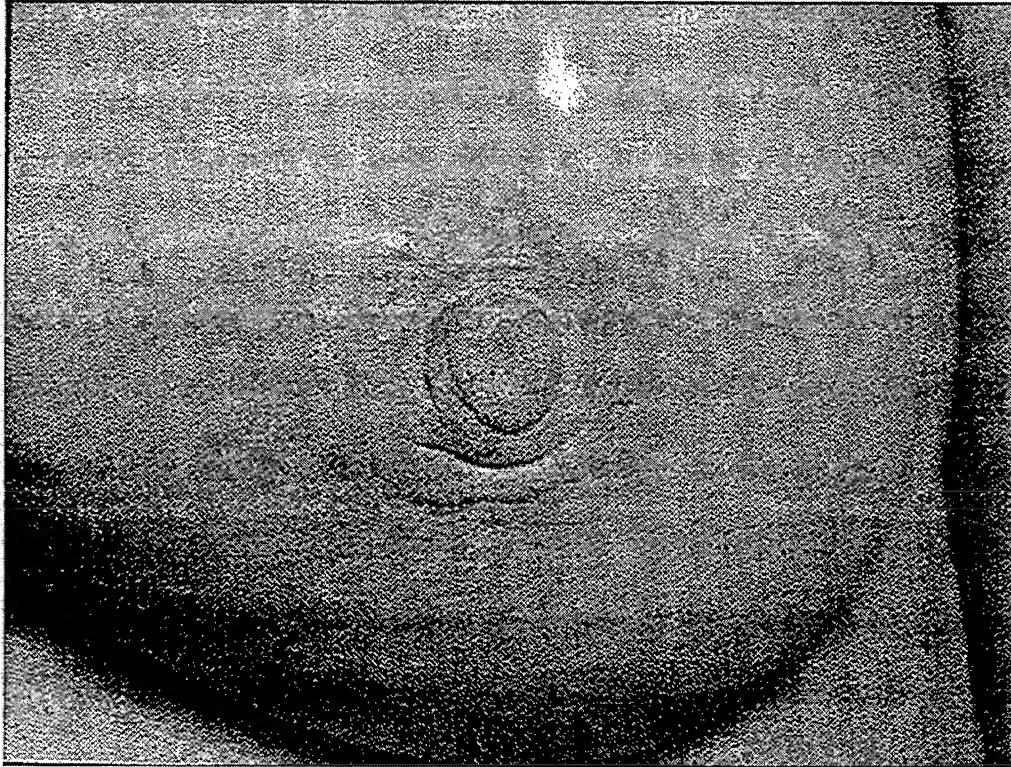
Slide Credit: American Cancer Society, Atlanta, GA. Public Domain.

SLIDE 206

This close up view of peau d'orange makes the orange-peel description obvious. Diagnosis is made by punch biopsy of the skin; if this is negative, open biopsy to include skin should be performed.

Source:

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.), *Textbook Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.



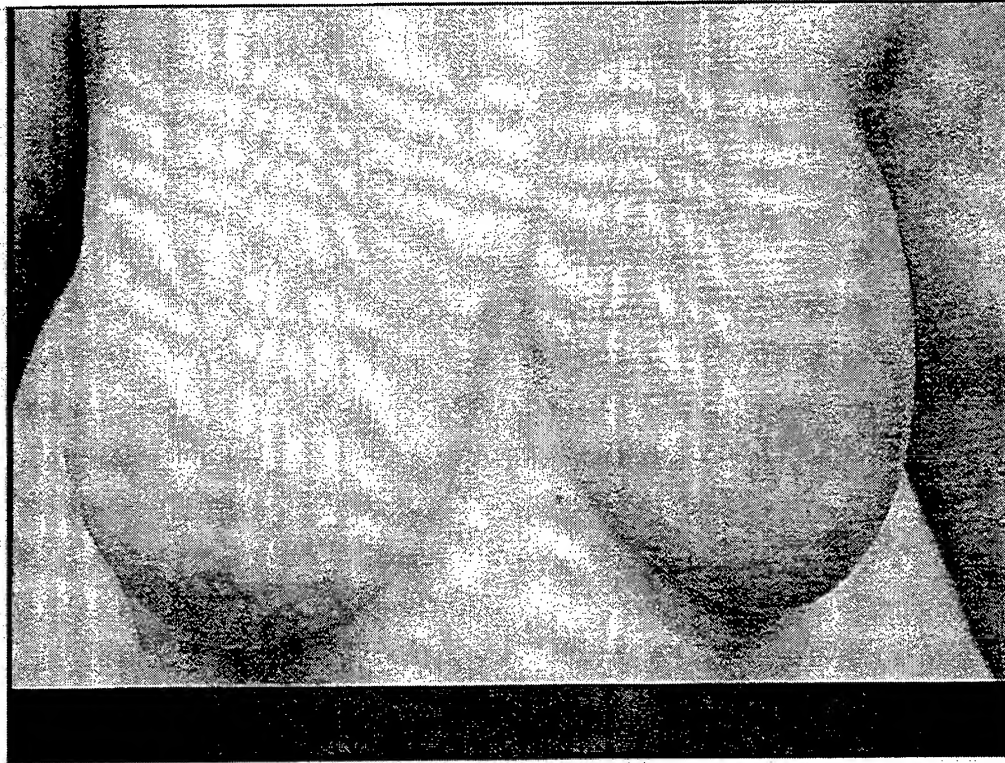
Slide Credit: from Mansel RE, Runderd NJ (Eds.), *Color Atlas of Breast Diseases*, Chapter 5, figure 5-6. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 207

Note the erythema, nipple retraction, and peau d'orange present in this case. This patient's symptoms, which included pain, resolved after being treated with broad-spectrum antibiotics. If she had not resolved with antibiotics within 2 weeks, referral would have been necessary to rule out inflammatory carcinoma.

Source:

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.), *Textbook Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.



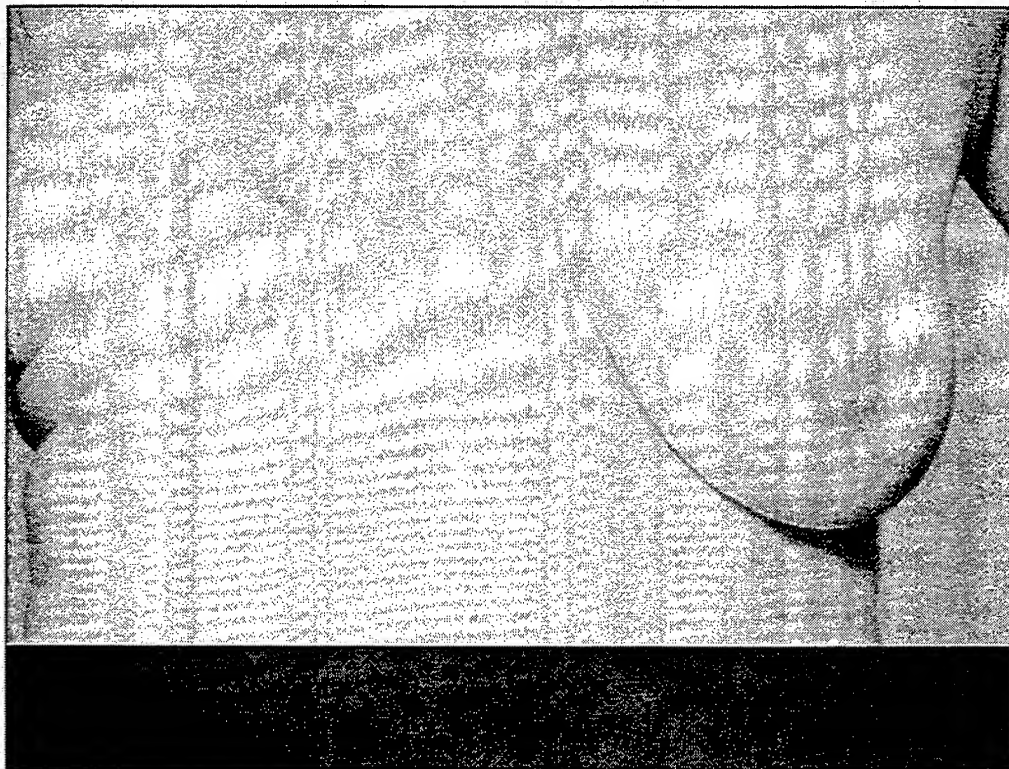
Slide Credit: from Mansel RE, Rundred NJ (Eds.), *Color Atlas of Breast Diseases*, Chapter 9, figure 9-6. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 208

Acute erythema can, but does not always occur as a reaction to radiation treatments. This woman's left breast is showing some sunburn-like effect from radiation. This condition can last up to a year after radiation therapy. It is common to develop peau d'orange from radiation therapy as well. Sometimes it becomes difficult to distinguish the etiology of these reactions and consultation with the specialist may be necessary to rule out inflammatory carcinoma.

Source:

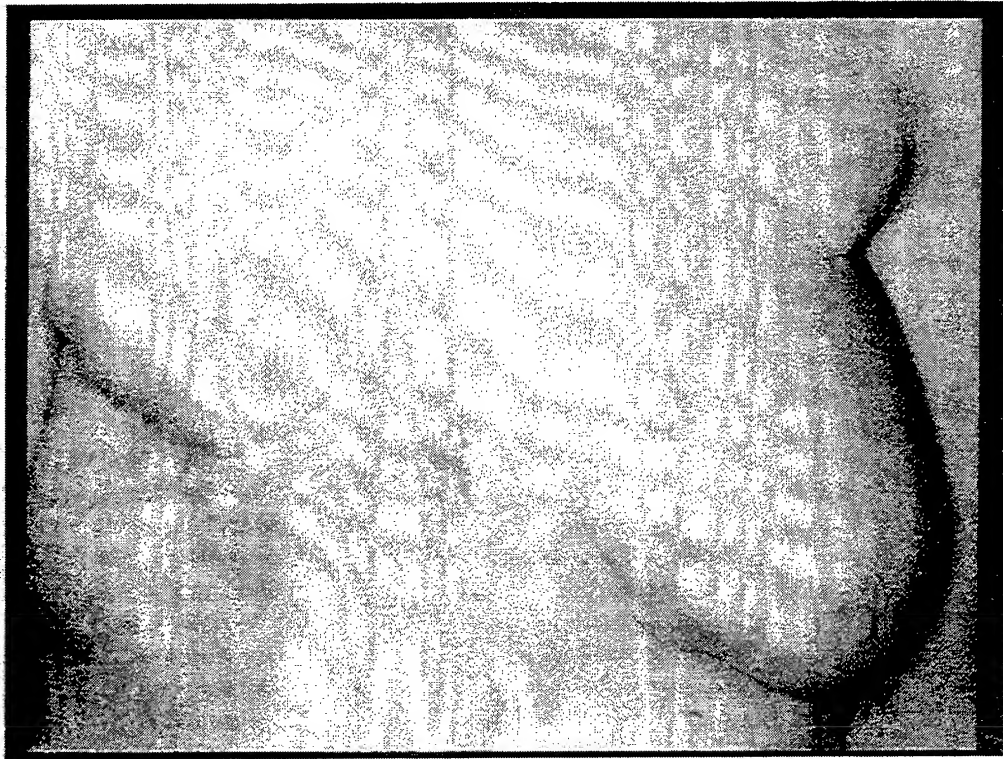
Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.). *Textbook Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.



Slide Credit: from Mansel RE, Rundred NJ (Eds.), *Color Atlas of Breast Diseases*, Chapter 8, figure 8-1. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 209

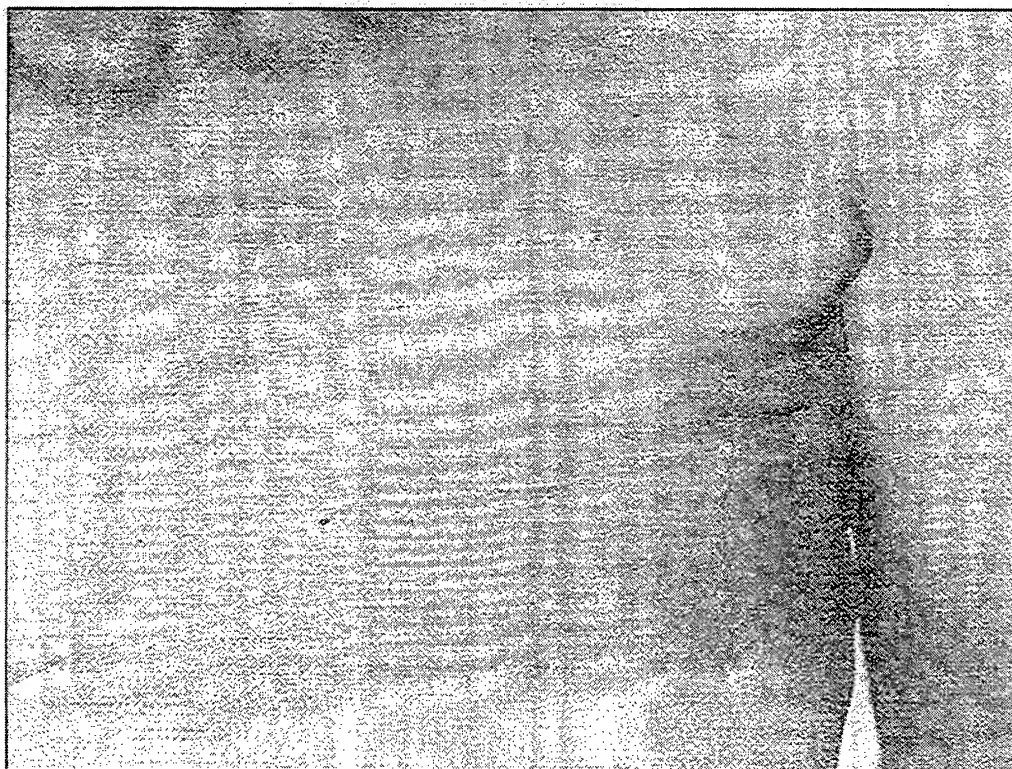
The appearance of erythematous nodules in a surgical site after breast cancer treatment is an ominous sign and usually represents a local recurrence. Post-treatment skin changes are often subtle. This event can occur years after primary treatment. Referral is indicated.



Slide Credit: from Hayes DF (Ed.). *Atlas of Breast Cancer*. Chapter 9, figure 9.24A. London: Mosby Europe Ltd., 1993.

SLIDE 210

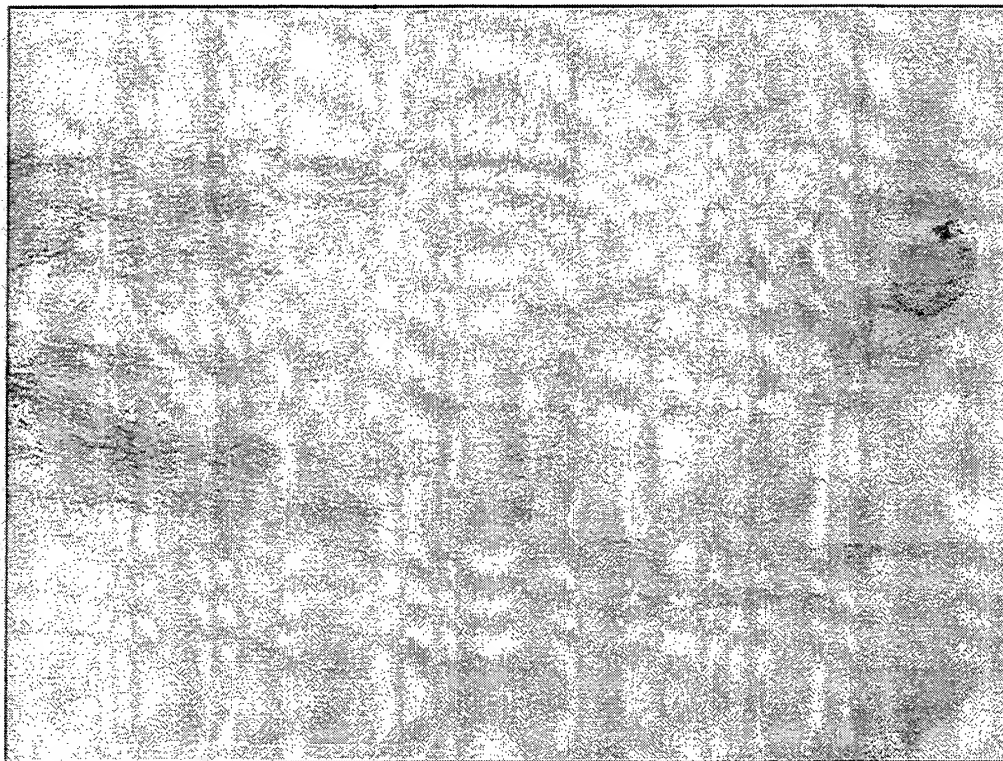
This slide demonstrates a chest wall recurrence that is a more advanced presentation of local recurrence.



Slide Credit: from Mansel RE, Runder NJ (Eds.), *Color Atlas of Breast Diseases*, Chapter 8, figure 8-3. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 211

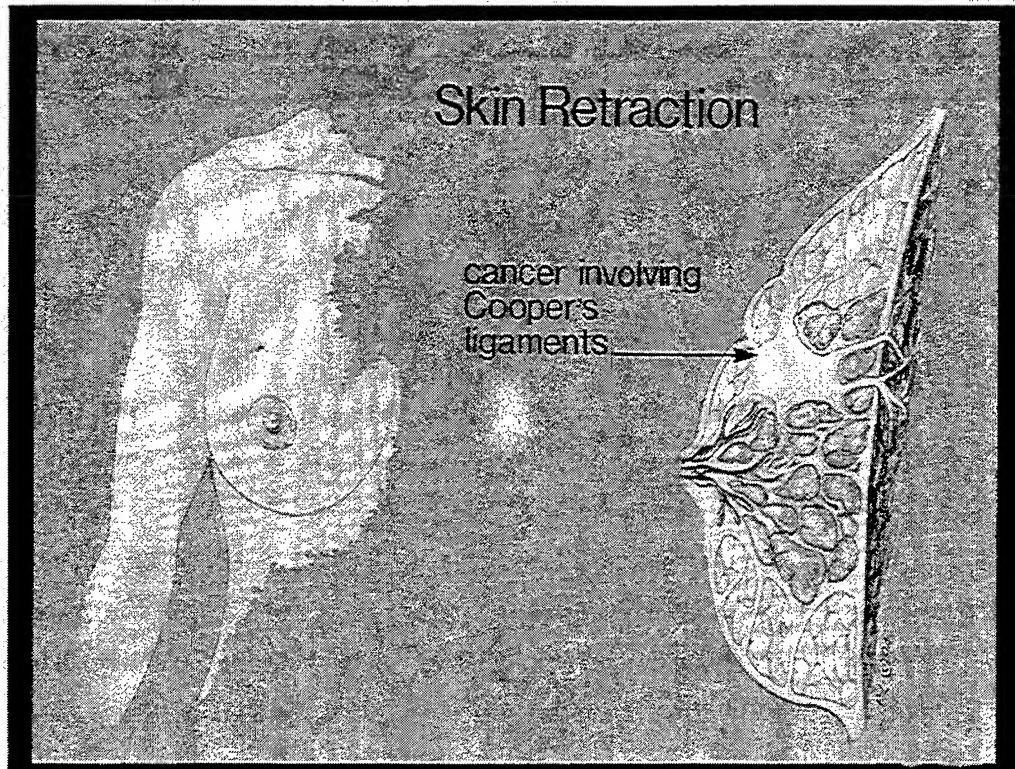
Sometimes a diffuse erythematous rash occurs at the site of previous breast cancer surgery. It often extends onto the back. This skin change represents a local recurrence and is very difficult to control.



Slide Credit: from Mansel RE, Rundred NJ (Eds.), *Color Atlas of Breast Diseases*, Chapter 8, figure 8-8. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 212

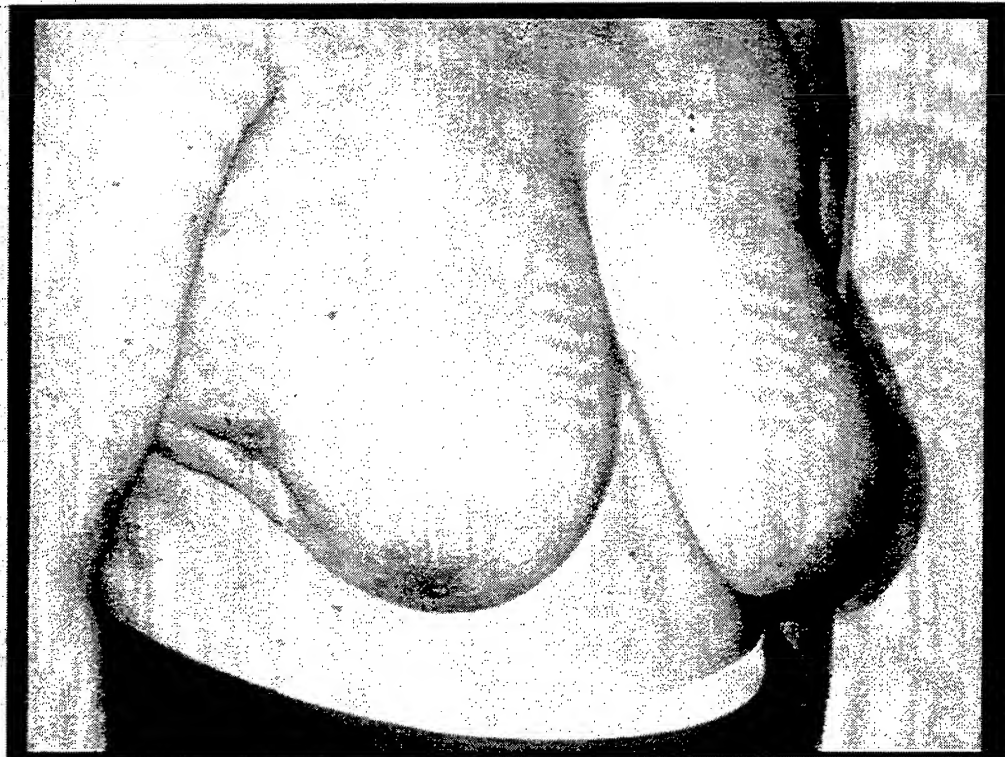
Sometimes radiotherapy can result in the proliferation of blood vessels known as telangiectasias. These are not raised and are harmless, although cosmetically unattractive. Telangiectasias often takes 4-5 years to develop.



Slide Credit: Slide No. 155 from Osuch JR, Dell DL, Sleighter S. *Breast and Cervical Cancer Education for Primary Care Providers*. Alexandria, VA: American Medical Women's Association, 1994, Joyce Lavery, MFA, CMI. Used with permission.

SLIDE 213

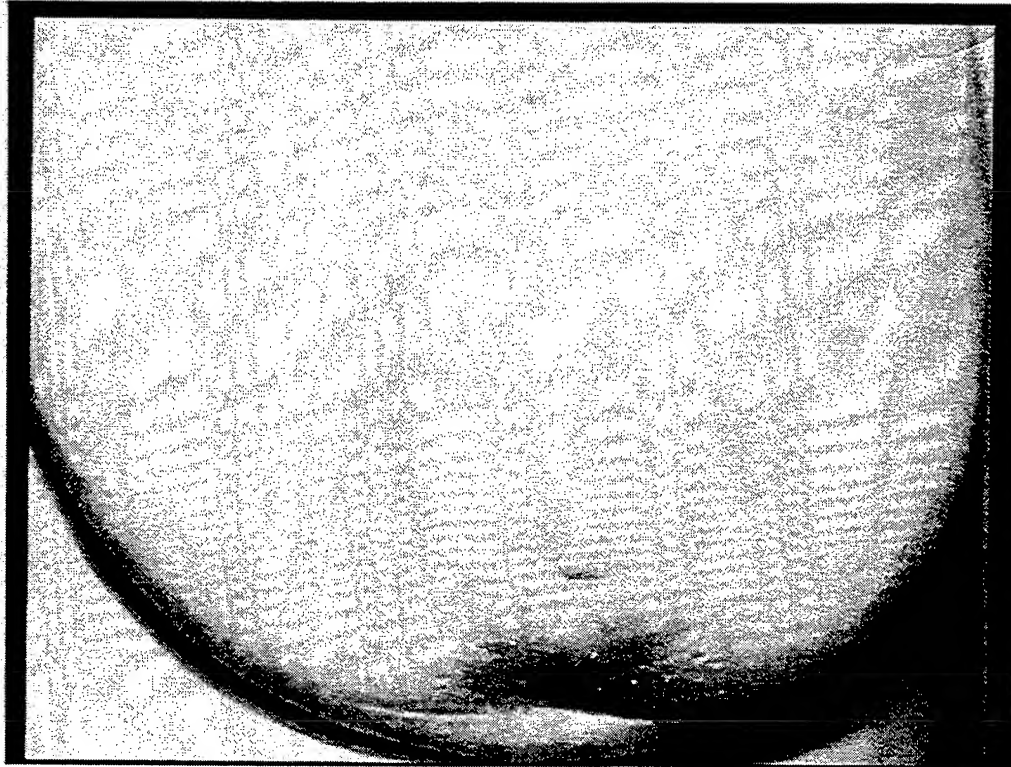
Skin retraction is almost always a sign of underlying carcinoma. It occurs secondary to involvement of Cooper's ligaments with carcinoma. Recall that Cooper's ligaments attach to both the skin and the pectoralis major muscle.



Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000. (Slide from personal collection of Janet Rose Osuch M.D., M.S.)

SLIDE 214

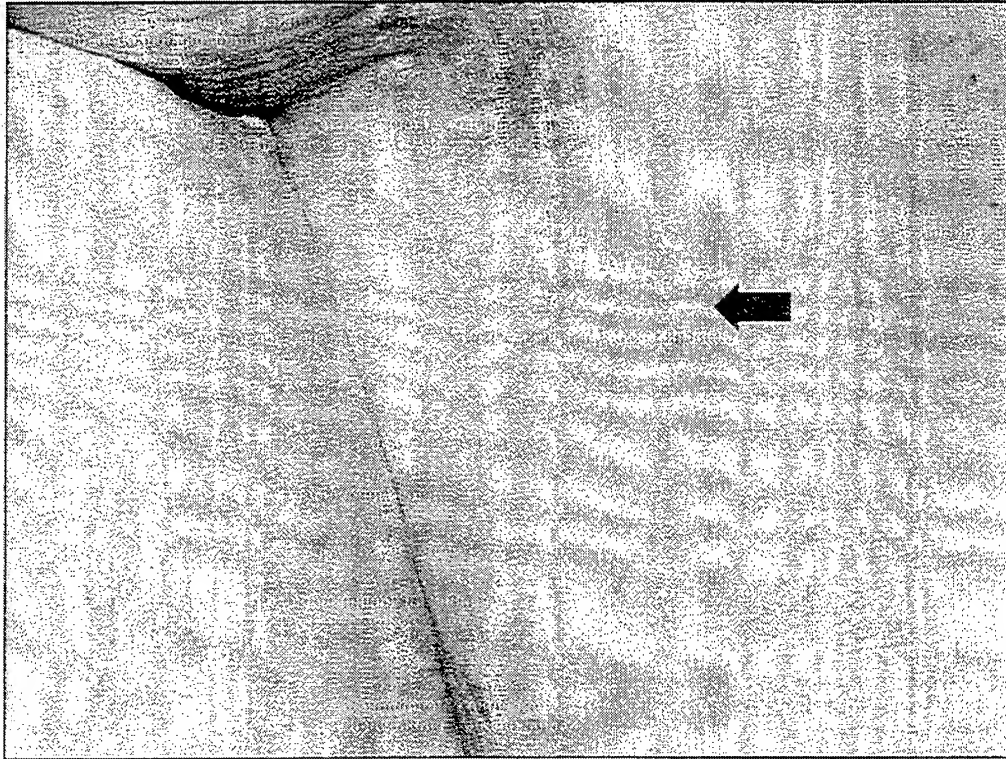
Advanced cases of skin retraction can be note with simple observation. This patient saw her doctor every 6 months for 8 years for hypertension, had never had a breast exam or a mammogram.



Slide Credit: from Blamey R, Evans A, Ellis I, et al. (Eds.). *Atlas of Breast Cancer*. Figure 4. Hampshire, UK: Merit Publishing International, 1994. Used with permission.

SLIDE 215

This is a picture of a woman with congenital nipple inversion who developed advanced subareolar skin retraction. This woman has cancer.



Slide Credit: from Blamey R, Evans A, Ellis I, et al. (Eds.). *Atlas of Breast Cancer*. Figure 5. Hampshire, UK: Merit Publishing International, 1994. Used with permission.

SLIDE 216

More subtle skin retraction may require arm raising, as shown here. The arrow shows the site of an underlying carcinoma.

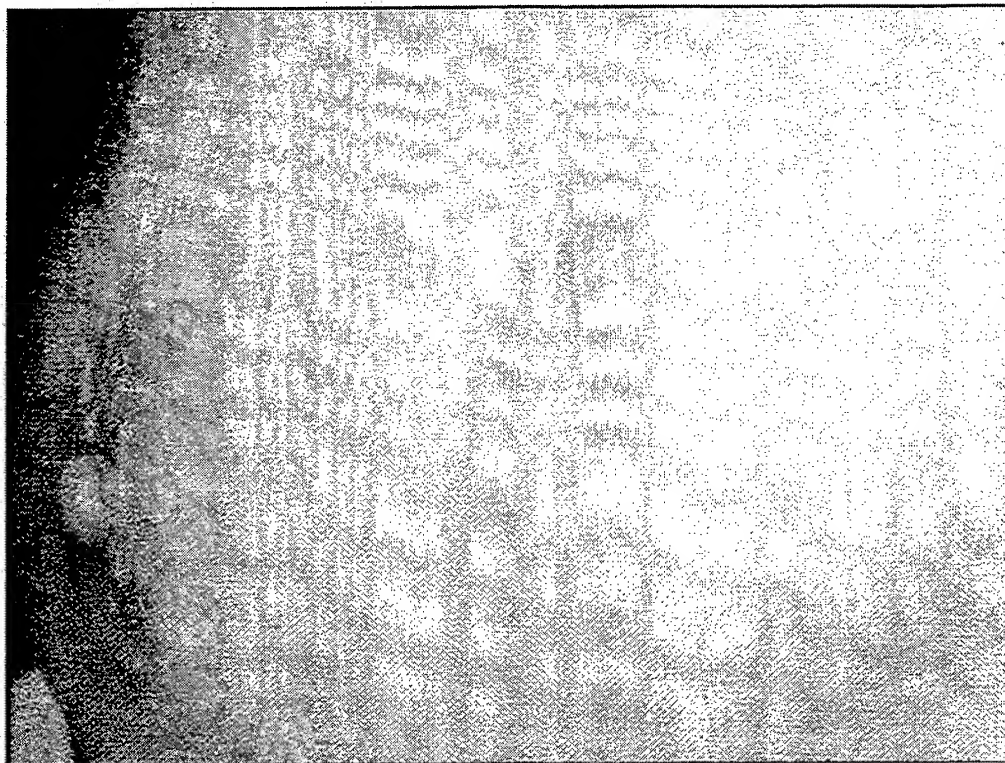


Slide Credit: from Blamey R, Evans A, Ellis I, et al. (Eds.). *Atlas of Breast Cancer*. Figure 98. Hampshire, UK: Merit Publishing International, 1994. Used with permission.

SLIDE 217

Contrast the previous slide with the skin retraction present along the course of a vein.

This is an example of Mondor's Disease, or thrombophlebitis of the lateral thoracoepigastric vein in the breast, usually due to surgery or trauma. If painful, it can be treated with oral analgesics. It resolves spontaneously within 2-6 weeks. The differential diagnosis includes carcinoma.



Slide Credit: from Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast – Concepts and Clinical Management*, Chapter 17, figure 17.4. London: Baillier Tindall, 1989. Used with permission.

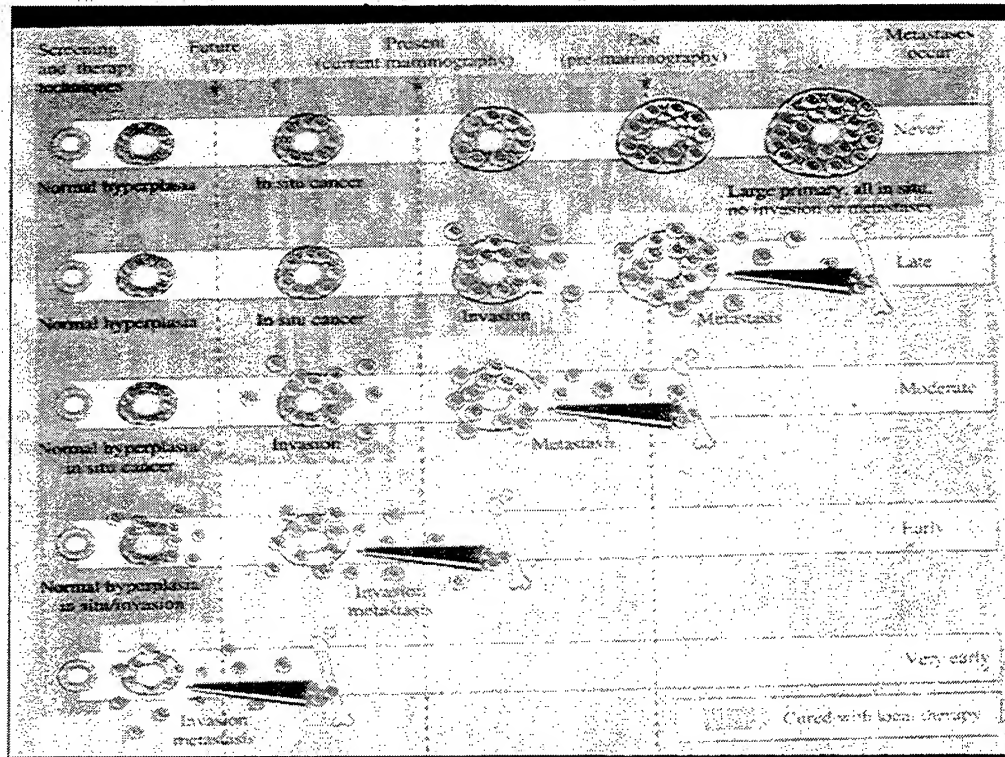
SLIDE 218

Sometimes skin dimpling will be elicited only with pectoralis major muscle contraction. The differential diagnosis in this case is carcinoma vs. Mondor's disease of a short segment of the lateral thoracoepigastric vein. Carcinoma is much more common and referral should be considered when this change is present. An algorithm summarizing the management of patients with observational findings of breast disease can be found in Appendix 7.

Source:

The duct ectasia /periductal mastitis complex. In: Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management*. London: Baillière Tindall, 1989.

BREAST CANCER HETEROGENEITY



Slide Credit: from Hayes DF (Ed.). *Atlas of Breast Cancer*. Chapter 1, figure 1-3B. London: Mosby Europe Ltd., 1993.

SLIDE 219

The whole goal of detection of breast cancer in the pre-clinical phase is to diagnose the disease prior to its ability to metastasize. This will not be possible in every patient. This slide reinforces the tremendous heterogeneity of breast cancer. The dark area represents those patients cured with local therapy, the light green represents those patients destined to die from metastatic breast cancer no matter when it is detected. The second dashed vertical line from the left represents the detection of occult breast cancer by mammography. The slide illustrates the principle that breast cancer has the ability to metastasize very early in some patients, long before the disease in the breast is detectable. This is illustrated in the bottom three rows of the slide. It becomes critical, therefore, that work up and follow up of breast problems follow standard protocols and that it be carefully documented.

Source:

Osuch JR. Bonham VL. Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. *Medscape Women's Health* 1998; Vol. 3, No. 5. <http://www.medscape.com>. (See instructions in Appendix 10.)

Principles of Risk Management for Breast Cancer

Screen According to Guidelines

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 220

Allegations of failure to screen for breast cancer are becoming increasingly common. Routine breast cancer screening through the use of mammography and CBE is universally recommended for women 50 and over. Evidence has accumulated to favor mammography use in women 40 and over on a routine basis as well. The screening schedule followed by the physician should be applied uniformly to the active patient population, with exceptions to the office's screening policy carefully documented. Documentation of assessment for breast cancer risk will become increasingly important in the future.

Source:

Osuch JR, Bonham VL. The timely diagnosis of breast cancer. *Cancer* 1994;74:271-278.

Principles of Risk Management for Breast Cancer

- **Assess risk**
- **Perform careful history and exam**
- **Examine specific area of concern**
- **Repeat exam at best phase of menstrual cycle in ovulating women**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University. 2000.

SLIDE 221

The most common allegation for failure to diagnose breast cancer is failure to be impressed with clinical findings or to verify a patient's complaint. In addition to a risk assessment, it is important to document a thorough history and CBE, to document the findings on CBE if the patient has a specific area of concern, and if the findings are subtle, to be sure the exam is at the best phase of the cycle in premenopausal women.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health 1998; Vol. 3, No. 5.
<http://www.medscape.com>. (See instructions in Appendix 10.)

Principles of Risk Management for Breast Cancer



***Follow every
breast
complaint to
resolution
or refer***

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 222

Asking a patient to call if the problem worsens is a suboptimal office policy from a risk management standpoint, as some patients will unconsciously deny their problems until they become more advanced. Instead, specific follow-up or referral is advised.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health 1998; Vol. 3, No. 5. <http://www.medscape.com>. (See instructions in Appendix 10.)

Principles of Risk Management for Breast Cancer

TRACK/COMMUNICATE

■ **Patient Compliance**

- with tests
- with follow up
 - ✧ office visits
 - ✧ referrals

■ **Results of Tests**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 223

Tracking of test results and recommendations for tests or referrals is a critical component of the risk management process. Results of tests need to be received before they can be reviewed and recommendations communicated. This includes results of referrals to other physicians. A method for ensuring the timely receipt of all ordered tests or referrals, with chart documentation of recommendations for follow up, is a necessary component of sound risk management. Many practices also use tracking systems to remind patients that they are due for check-ups, and this policy promotes communication and good patient care.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health 1998; Vol. 3, No. 5. <http://www.medscape.com>. (See instructions in Appendix 10.)

Principles of Risk Management for Breast Cancer:

Components of Successful Medical Malpractice

- **Duty**
- **Negligence**
- **Causation**
- **Damages**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 224

The components of a successful medical malpractice lawsuit include issues related to duty, negligence, proof that the negligence caused harm to the patient, and that economic, non-economic, or punitive damages resulted. Especially important in the risk management of a non-compliant patient is the principle of duty.

Source:

Dewar MA. Legal issues in breast disease. In: Bland KI, Copeland EM (Eds.) *The Breast-Comprehensive Management of Benign and Malignant Disease, 2nd Edition*. Philadelphia, PA: W.B. Saunders, 1998; pp. 1577-1587.

Principles of Risk Management for Breast Cancer: The Non-Compliant Patient

"What are my obligations?"

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 225

Duty refers to the legal responsibility that a doctor assumes whenever a patient is accepted into the practice. The responsibility assumes that both reasonable and appropriate care have been rendered to the patient. This is an impossible task if the patient does not follow recommendations for follow up. Most physicians are troubled to learn that non-compliance on the patient's part does not excuse the doctor's legal responsibility to the patient. It is at these times that tracking and follow up, in conjunction with careful chart documentation is critical. If the patient continues to be resistant to recommendations, it may be best to formally curtail the legal responsibility inherent in the doctor-patient relationship. Most physicians find this concept contrary to their ethical codes of conduct regarding patient care. It is important to realize, however, that good patient care implies mutual trust and that it may be in the best interest of the patient to refer her to a physician who may better meet her needs.

Source:

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health 1998; Vol. 3, No. 5. <http://www.medscape.com>. (See instructions in Appendix 10.)

Risk Management for Breast Problems: Absolute Indications for Referral

- **Nonpalpable mammographic abnormality read as suspicious**
- **Any discrete abnormality not examined further by primary care provider**
- **Rapidly recurring breast cyst that recurs twice on follow up**
- **Aspirated cyst that is grossly bloody**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 226

While many breast complaints can be followed and resolved by primary care providers, the following are absolute indications for a surgical referral:

- Nonpalpable mammographic abnormality read as suspicious
- Any discrete abnormality not examined further by the primary care provider
- Rapidly recurring breast cyst (within 4-6 weeks) that recurs a second time within 4-6 weeks
- Aspirated cyst that is grossly bloody

Source:

Osuch JR, Bonham VL. The timely diagnosis of breast cancer. *Cancer* 1994;74:271-278.

Risk Management for Breast Problems: Absolute Indications for Referral

- **Palpable asymmetric mass or thickening solid after aspiration and either not evaluated or not benign by triple diagnosis**
- **Spontaneous unilateral single-duct nipple discharge**
- **Nipple scaling that does not respond to hydrocortisone treatment within 2 weeks**
- **Skin or nipple retraction**
- **Skin erythema that does not respond to antibiotic treatment within 2 weeks**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Züber TJ. Michigan State University, 2000.

SLIDE 227

- Palpable asymmetric mass or thickening solid after aspiration and either not evaluated or
not benign by triple diagnosis
- Spontaneous unilateral single-duct nipple discharge
- Nipple scaling that does not respond to hydrocortisone treatment within 2 weeks
- Skin or nipple retraction
- Skin erythema that does not respond to antibiotic treatment within 2 weeks.

Source:

Osuch JR, Bonham VL. The timely diagnosis of breast cancer. *Cancer* 1994;74:271-278.

Risk Management for Breast Problems: Relative Indications for Referral

- **Nonpalpable mammographic abnormalities read as indeterminate**
- **Bilateral multiple-duct nipple discharge**
- **Women with difficult breast examinations**
- **Women at high risk for development of breast cancer**
- **Patients needing added reassurance**
- **Lack of an effective physician-patient relationship in relation to breast care**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 228

Relative indications for referral include:

- Nonpalpable mammographic abnormalities read as indeterminate
- Bilateral multiple-duct nipple discharge
- Women with difficult breast examinations
- Women at high risk for development of breast cancer
- Patients needing added reassurance
- Evidence of lack of an effective physician-patient relationship in relation to breast care.

A summary of risk management principles for common allegations of failure to diagnose breast cancer can be found in Appendix 9.

Source:

Osuch JR, Bonham VL. The timely diagnosis of breast cancer. *Cancer* 1994;74:271-278.

Clinical Skills - CBE

The Clinical Breast Examination (CBE)

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 229

Historically, the clinical breast exam (CBE) has been a neglected part of the physical examination. In the 1950s a survey was done indicating that 30% of women who requested a complete history and physical examination from their physician did not have even a cursory examination of their breasts.

Many physicians express concern regarding lack of adequate training of CBE in medical school. CBE is an often-skipped portion of clinical skills training, sometimes being allocated to OB/GYN clerkships, sometimes being included as an afterthought during pelvic and rectal exam training, and rarely reinforced during clerkship residency years in any formal way.

In addition, once formal training of CBE is done, many physicians complain that doing a proper exam requires an unrealistic amount of time. We must challenge ourselves, however, to consider the fact that breast cancer and breast disease are prevalent conditions that are often asymptomatic. Performing a thorough CBE will often lead to discovery of unsuspected disease, with higher yield than other parts of the routine physical exam, especially in the asymptomatic ambulatory patient.

Source:

Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition*. Philadelphia, PA: W.B. Saunders Co., 1986.

Clinical Skills - CBE

***Normal CBE =
Absence of Abnormality***

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

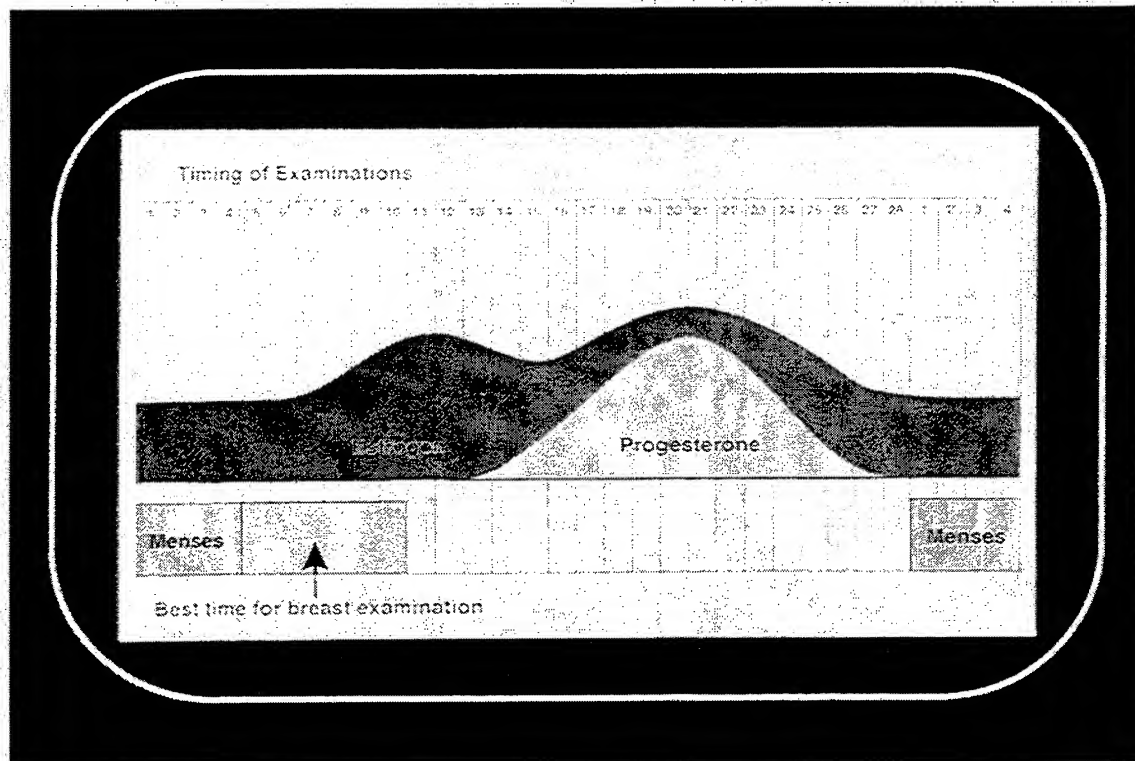
SLIDE 230

Interpretation of CBE can be challenging, and requires confidence for proficiency in interpretation. This is achieved as with any other skill--through practice. It is time to actively discourage the practice of reporting breast exam results as "deferred," or worse, of not even including the breasts as a portion of the physical exam deserving comment.

Consider the physical exam of the heart. When one places a stethoscope in the fifth intercostal space in the mid-clavicular line on the left side of the chest, the same heart sounds are auscultated in every normal patient. However, the breast exam is not so uniform. As we have discussed, the breast exam changes markedly throughout a woman's lifecycle. The exam is most challenging in women 35-55. Before this time, most women have dense breasts with a smooth but firm sensation on palpation. Between 35-55, the breasts are much more nodular, with a popcorn-like bumpy background. After menopause, the breasts should be smooth and soft, with little nodularity. Some women believe that their breasts "have always been lumpy". It is helpful to provide feedback during CBE regarding the relative nodularity of the breasts according to the woman's stage of the lifecycle.

Source:

Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.). *Disease of the Breast, 3rd Edition*. Philadelphia, PA: W.B. Saunders Co., 1986.



Slide Credit: Slide No. 20 from Osuch JR, Dell DL, Sleighter S. *Breast and Cervical Cancer Education for Primary Care Providers*. Alexandria, VA: American Medical Women's Association, 1994. Joyce Lavery MFA, CMI. Modified after John A Craig, M.D., Illustrator. In: Townsend, CM. *Breast Lumps*. New Jersey: Ciba Pharmaceutical Company, Clinical Symposia 1080, 32:7. Used with permission.

SLIDE 231

Not only is the CBE interpretation different in every woman, but the exam can be different in the same woman if she is premenopausal. As previously discussed, the breast tissue responds to the secretion of progesterone in the latter half of the ovarian cycle with engorgement of tissue and increased nodularity. Consequently, the breasts may be tender and nodular during the luteal phase of the cycle. Interpretation of CBE may in turn be difficult and it is best to ask a woman to return for a repeat examination in the best phase of her ovarian cycle if there is any question of an asymmetry between one breast and the other. The optimal time to interpret the breast exam in a premenopausal woman is 3-10 days after the onset of menses. It can be difficult to determine optimal timing in a premenopausal woman who has had her uterus removed. Asking her to return in approximately 6 weeks to examine her in a different phase of her ovarian cycle is helpful if the CBE interpretation is difficult. It is not useful to ask a post-menopausal woman with an abnormal CBE to follow up for repeat exam, because she should not be undergoing dynamic breast changes because her ovarian function has ceased. Her abnormality needs immediate work up.

Source:

Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.). *Disease of the Breast, 3rd Edition*. Philadelphia, PA: W.B. Saunders Co., 1986.

The Clinical Breast Examination

The **FOCUSED HISTORY**

- 1. BSE Performance**
- 2. Breast Lump**
- 3. Nipple Discharge**
- 4. Skin Changes**
- 5. Breast Pain**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 232

As with any clinical examination, CBE begins with a focused history that should include a risk factor profile and questions regarding possible breast symptoms, as listed here. We have discussed these portions of the focused history during the morning session. The breast self-examination portion of the history is especially important when the patient presents with a breast complaint. Be sure to discuss with the patient how often she does BSE and at which phase of the menstrual cycle. Ask if she performs her exam in the shower, lying down, or both. The clinical breast exam is the ideal setting for teaching breast self-exam.

Source:

Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.). *Disease of the Breast, 3rd Edition*. Philadelphia, PA: W.B. Saunders Co., 1986.

Clinical Skills - CBE

Observation

- **Size**
- **Symmetry**
- **Shape**
- **Skin Color**
- **Skin Texture**
- **Nipple/Areola**
- **Skin Retraction**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 233

Physical examination of the breast begins with observation. It is important to assess size, symmetry between the two breasts, shape, skin color, texture of the skin, appearance of the nipple-areolar complex, and the presence or absence of skin retraction.

Sources:

1. Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition*. Philadelphia, PA: W.B. Saunders Co., 1986.
2. Barton MB, Harris R, Fletcher SW. Does this patient have breast cancer? The screening clinical breast examination: should it be done? How? *JAMA* 1999; 282:1270-1280.



Slide Credit: American Cancer Society, Atlanta, GA., Public Domain

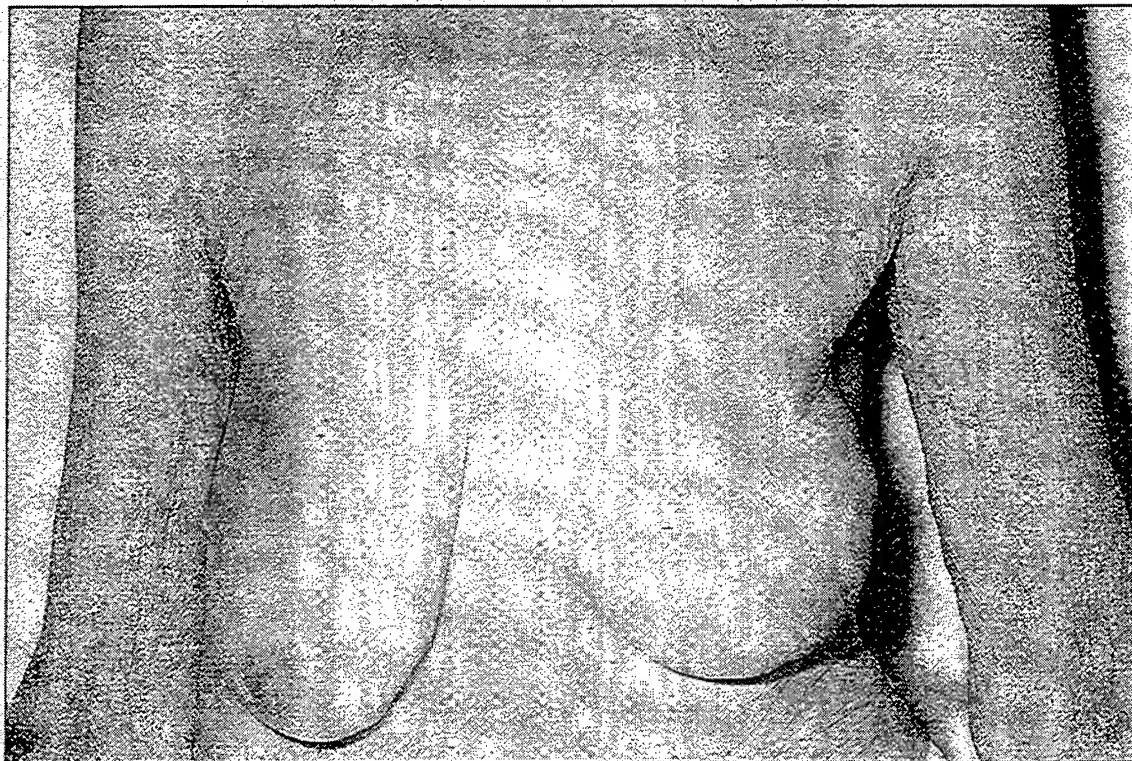
SLIDE 234

Observe the patient from the front in the sitting position. Visualize the internal anatomy and location of the breast tissue over the pectoralis major and serratus anterior muscles.

Some physicians express concerns about embarrassing the patient with this and other maneuvers of observation. This portion of the exam lasts seconds and the patient is unlikely to feel uncomfortable if the physician approaches it with confidence and compassion. It is often helpful to have a third person present for the exam, be it a family member, friend, or office assistant.

Sources:

1. Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition*. Philadelphia, PA: W.B. Saunders Co., 1986.
2. Barton MB, Harris R, Fletcher SW. Does this patient have breast cancer? The screening clinical breast examination: should it be done? How? *JAMA* 1999; 282:1270-1280.



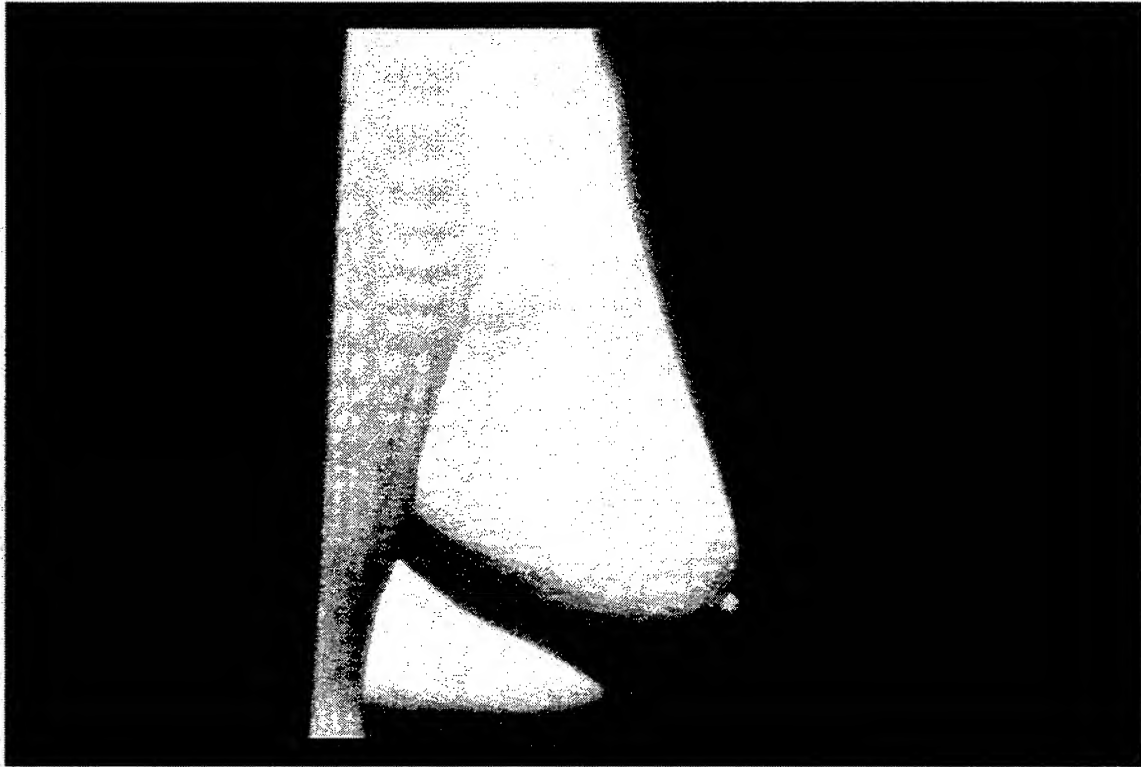
Slide Credit: from Mansel RE, Rundred NJ (Eds.), *Color Atlas of Breast Diseases*, Chapter 7, figure 7.3. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 235

The exam of a woman in the sitting position provides important clues to the presence of carcinoma which may not be appreciated if the observation component of the exam is omitted. The changes in size, shape and symmetry of the left breast as compared to the right demonstrated on this slide are facilitated by simultaneous observation of the breast. Whenever the height of the nipple varies between breasts, carcinoma should be suspected.

Source:

Mansel RE, Bundred NJ. *Color Atlas of Breast Diseases*. London: Mosby-Wolfe, 1995.



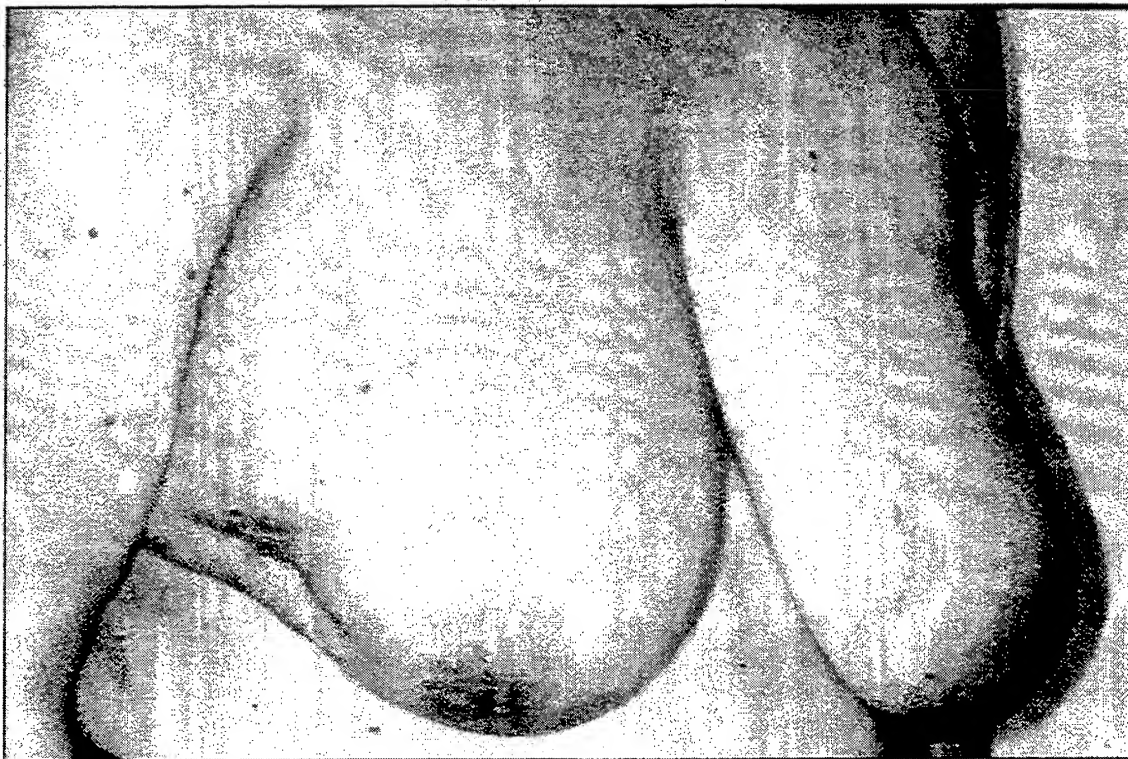
Slide Credit: American Cancer Society, Atlanta, GA., Public Domain

SLIDE 236

Observe the breasts on each side as well as from the front. Remember that when the patient's arms are at her sides, part of the skin of the breast is covered. Especially in larger breasted women, the breast tissue will extend over the serratus anterior muscle and be covered by the arm.

Sources:

1. Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition*. Philadelphia, PA: W.B. Saunders Co., 1986.
2. Barton MB, Harris R, Fletcher SW. Does this patient have breast cancer? The screening clinical breast examination: should it be done? How? *JAMA* 1999; 282:1270-1280.



Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000. (Slide from personal collection of Janet Rose Osuch M.D., M.S.)

SLIDE 237

You have already seen this slide. It illustrates the findings, sometimes not subtle, than can be observed through a simple inspection of the lateral aspect of the breast.



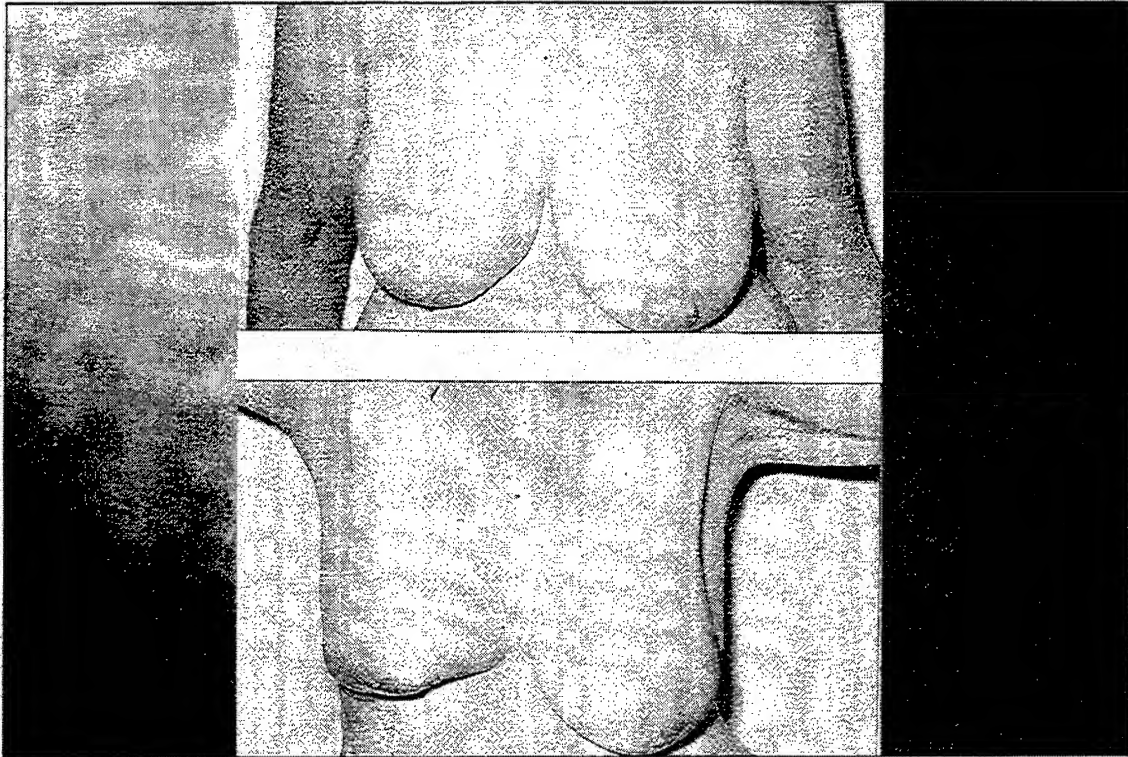
Slide Credit: American Cancer Society, Atlanta, GA., Public Domain

SLIDE 238

The next step in CBE is to have the patient lift her arms over her head. This exposes the lateral sides and inferior portions of the breast. Again, you will be observing size, symmetry, shape, skin color, skin texture, the appearance of the nipple-areolar complex, and the presence or absence of skin retraction. Remember to conduct this portion of the examination from the front and sides of the patient as well.

Sources:

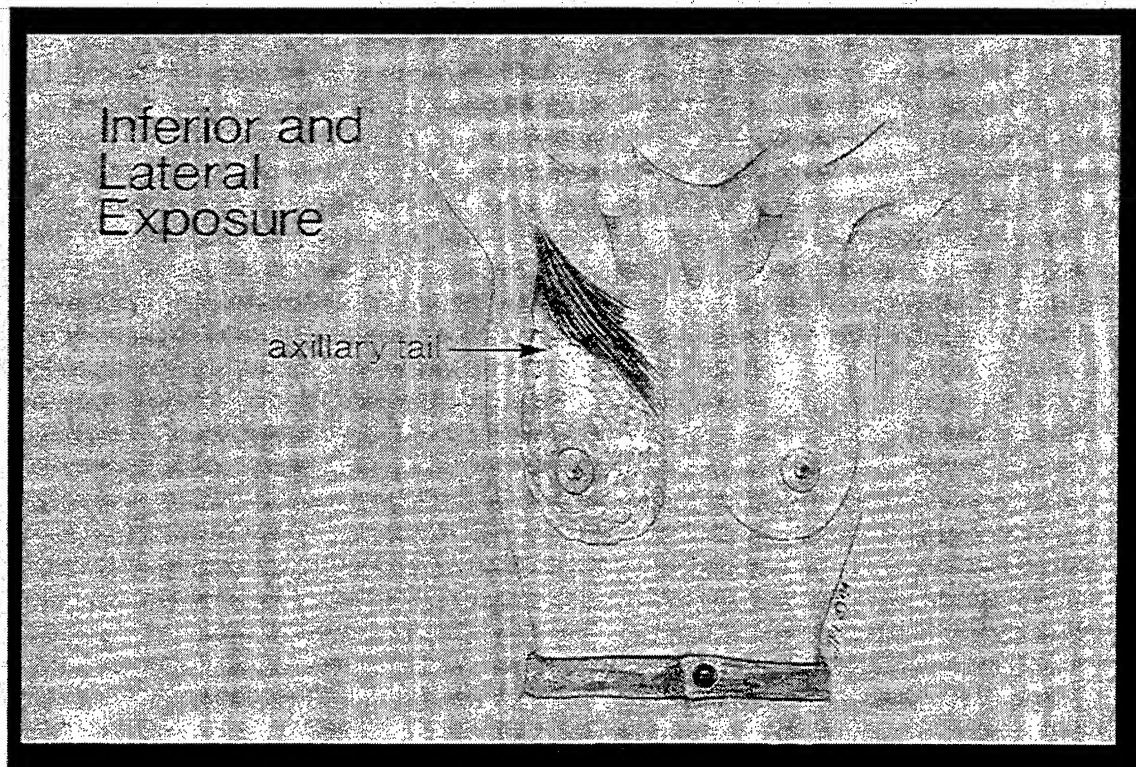
1. Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition*. Philadelphia, PA: W.B. Saunders Co., 1986.
2. Barton MB, Harris R, Fletcher SW. Does this patient have breast cancer? The screening clinical breast examination: should it be done? How? *JAMA* 1999; 282:1270-1280.



Slide Credit: from Mansel RE, Rundred NJ (Eds.), *Color Atlas of Breast Diseases*, Chapter 7, figure 7.4-7.5. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 239

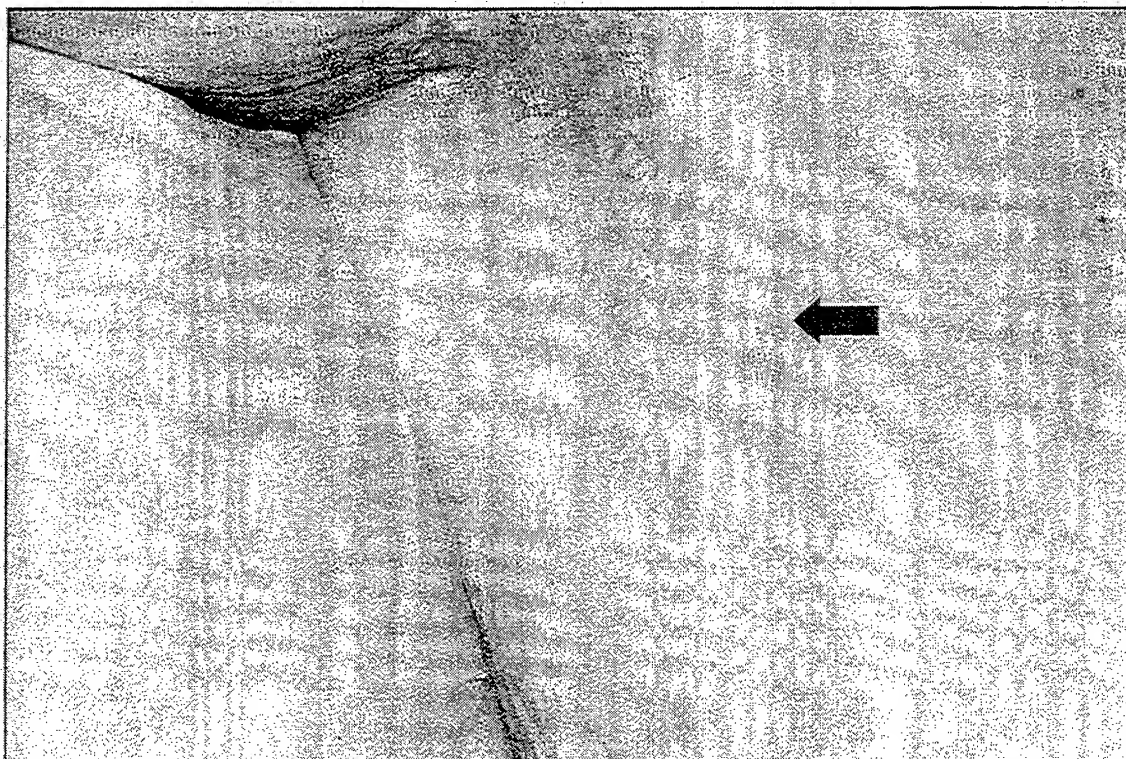
This slide illustrates the importance of the maneuver just discussed. In the sitting position with the arms at the sides, this patient's right breast is smaller than the left. In this setting, it is important to ask the patient if her breasts have been asymmetrical since adolescence. If she answers affirmatively, the finding is considered normal. If the patient indicates that the finding is new or of gradual onset, be prepared to search for an abnormality on CBE. Asking the patient to raise her arms above her head demonstrates obvious retraction of the lower inner portion of the breast in this slide.



Slide Credit: Slide No. 87 from Osuch JR, Dell DL, Sleighter S. *Breast and Cervical Cancer Education for Primary Care Providers*. Alexandria, VA: American Medical Women's Association, 1994, Joyce Lavery, MFA, CMI. Used with permission.

SLIDE 240

Remember that arm raising exposes the surface anatomy of the axillary tail of the breast.



Slide Credit: from Blamey R, Evans A, Ellis I, et al. (Eds.). *Atlas of Breast Cancer*. Figure 5. Hampshire, UK: Merit Publishing International, 1994. Used with permission.

SLIDE 241

Arm raising alone can be enough to elicit the sign of skin dimpling. You have also seen this slide previously. It demonstrates skin retraction of the axillary tail of the breast, and would not be observed if the arm raising maneuver was omitted.



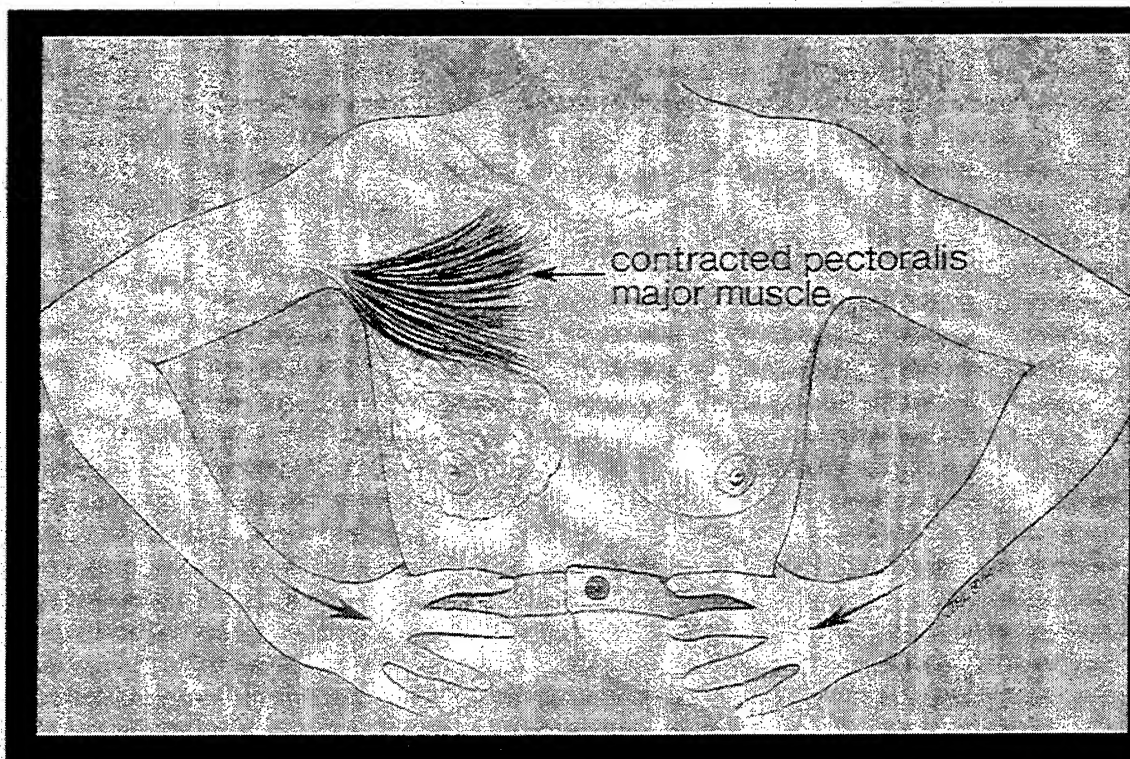
Slide Credit: American Cancer Society, Atlanta, GA., Public Domain

SLIDE 242

Next ask the patient to place her hands on her hips and to push in tightly. This causes contraction of the pectoralis major muscles.

Sources:

1. Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition*. Philadelphia, PA: W.B. Saunders Co., 1986.
2. Barton MB, Harris R, Fletcher SW. Does this patient have breast cancer? The screening clinical breast examination: should it be done? How? *JAMA* 1999; 282:1270-1280.



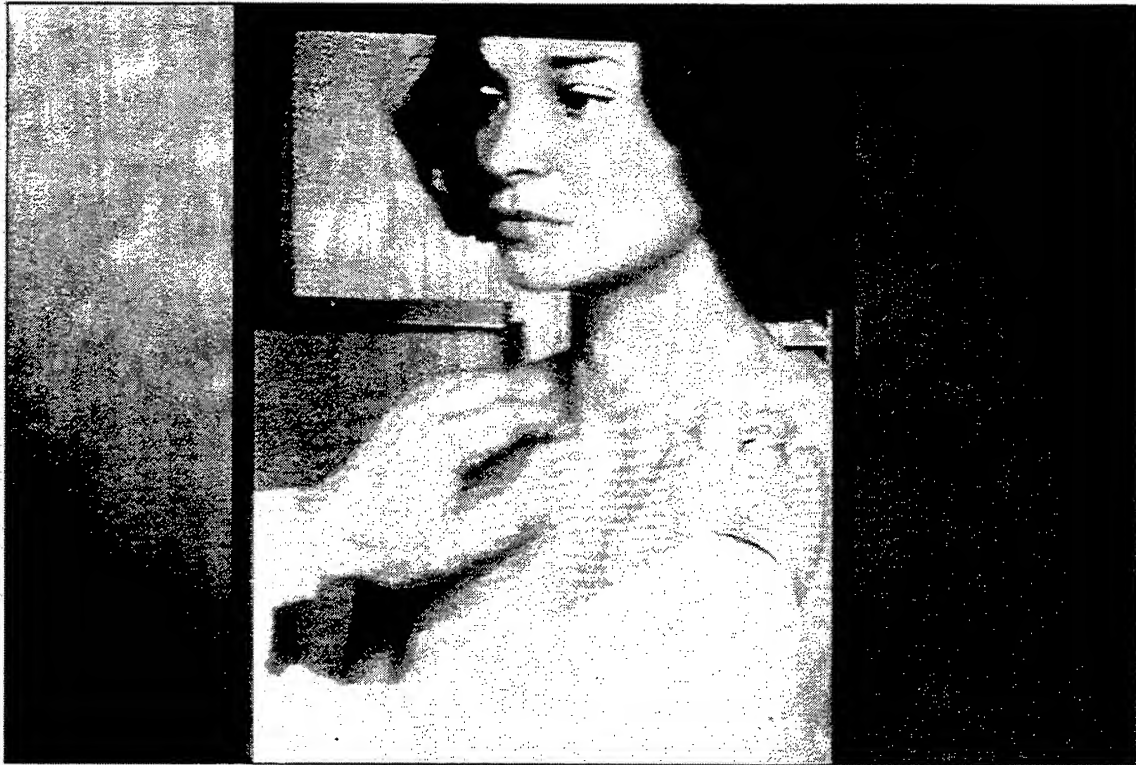
Slide Credit: Slide No. 89 from Osuch JR, Dell DL, Sleighter S. *Breast and Cervical Cancer Education for Primary Care Providers*. Alexandria, VA: American Medical Women's Association, 1994, Joyce Lavery, MFA, CMI. Used with permission.

SLIDE 243

If there is a tumor involving Cooper's ligaments, contraction of the pectoralis major muscle will cause skin retraction. The pathophysiology of this finding is related to breast anatomy. Contraction of the pectoralis major muscle results in shortening of Cooper's ligaments, which have attachments on the fascia of the muscle as well as the fascia under the skin.

Sources:

1. Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition*. Philadelphia, PA: W.B. Saunders Co., 1986.
2. Barton MB, Harris R, Fletcher SW. Does this patient have breast cancer? The screening clinical breast examination: should it be done? How? *JAMA* 1999; 282:1270-1280.



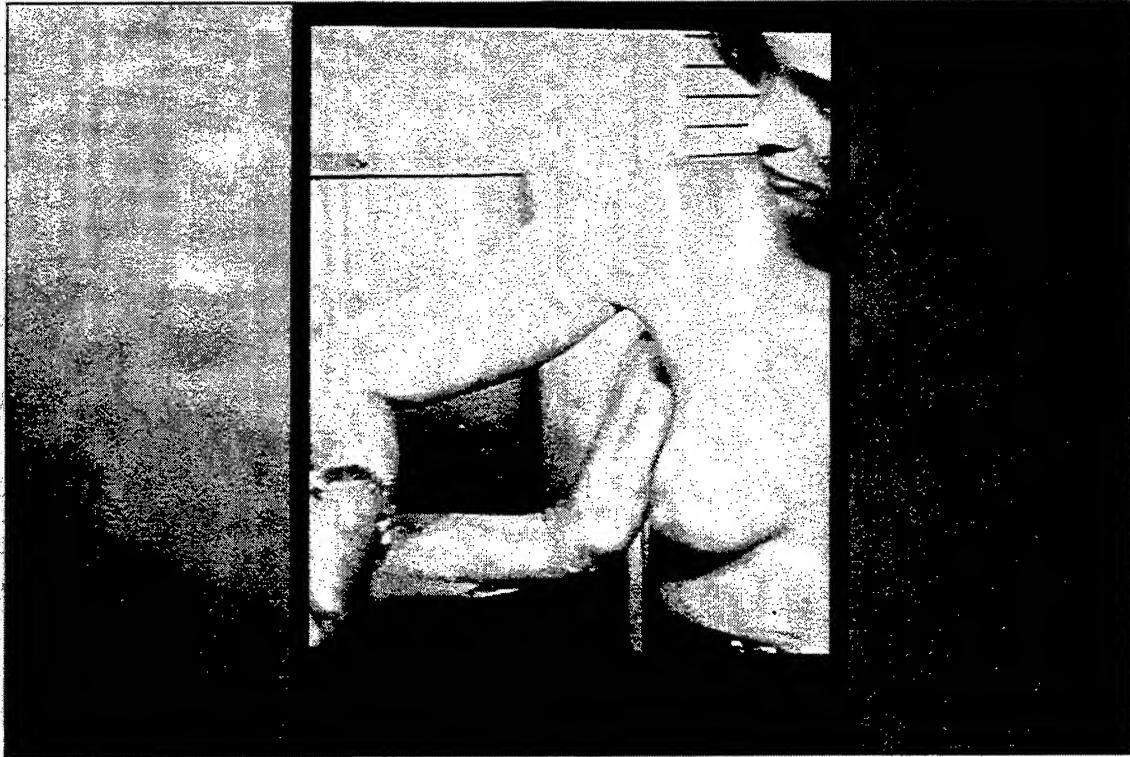
Slide Credit: American Cancer Society, Atlanta, GA., Public Domain

SLIDE 244

The next step is examination of the supraclavicular and infracavicular nodes by palpation. This is done by simultaneous bilateral palpation, first above the clavicle, and then below.

Sources:

1. Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition*. Philadelphia, PA: W.B. Saunders Co., 1986.
2. Barton MB, Harris R, Fletcher SW. Does this patient have breast cancer? The screening clinical breast examination: should it be done? How? *JAMA* 1999; 282:1270-1280.



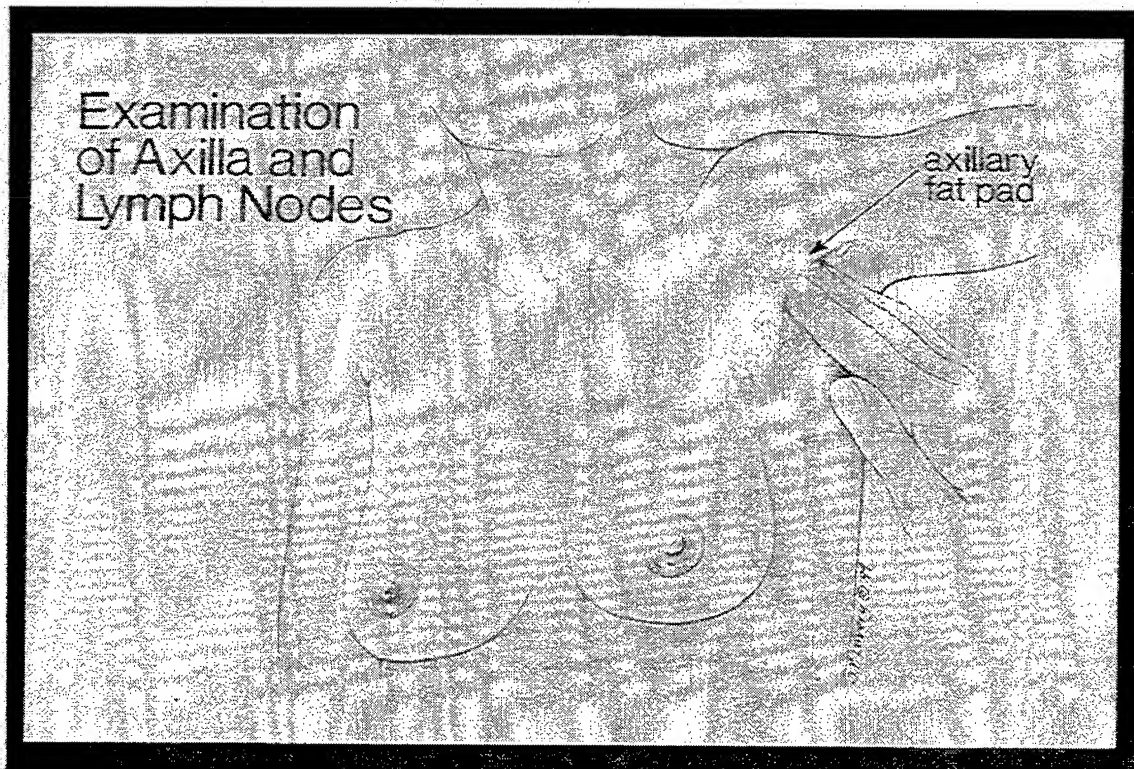
Slide Credit: American Cancer Society, Atlanta, GA., Public Domain

SLIDE 245

The next step is examination of the axillary lymph nodes. This is done in the sitting position. The physician should support the woman's arm at the elbow so that the arm and pectoralis muscles are relaxed. The examining hand can then palpate the axillary lymph nodes.

Sources:

1. Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition*. Philadelphia, PA: W.B. Saunders Co., 1986.
2. Barton MB, Harris R, Fletcher SW. Does this patient have breast cancer? The screening clinical breast examination: should it be done? How? *JAMA* 1999; 282:1270-1280.



Slide Credit: Slide No. 94 from Osuch JR, Dell DL, Sleighter S. *Breast and Cervical Cancer Education for Primary Care Providers*. Alexandria, VA: American Medical Women's Association, 1994, Joyce Lavery, MFA, CMI. Used with permission.

SLIDE 246

Many physicians skip the examination of the breast in the sitting position. There are three excellent reasons why this part of the exam should be done. First, when the woman is in a sitting position, the axillary fat pad moves forward, allowing access to the nodes. In the supine position, the fat pad falls back and up, making the lymph nodes less accessible to examination.

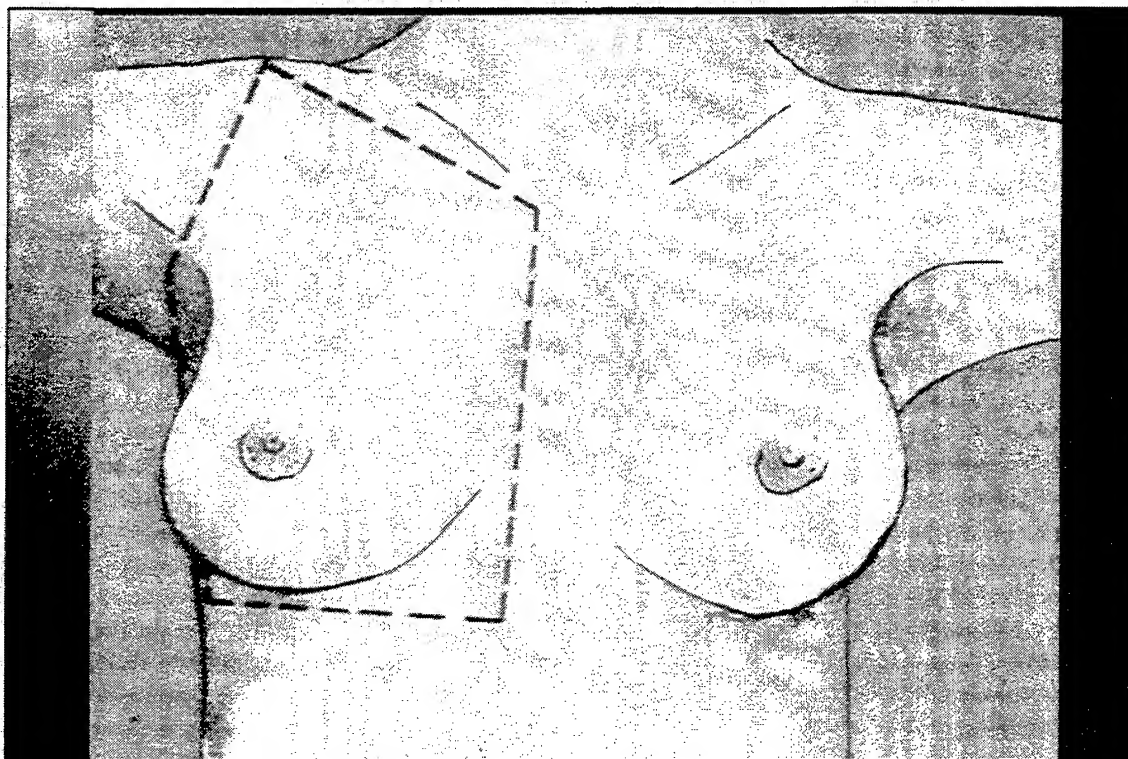
Second, many women palpate abnormalities doing BSE in the shower. If this is the case, the area of concern should be palpated with the patient sitting, especially if it cannot be felt with the patient supine.

Third, observation for skin retraction on pectoralis major contraction is difficult with the patient in a supine position.

An easy way to incorporate the sitting portion of the clinical breast exam during a routine physical exam is immediately before or after auscultation of the lungs. If done at this time, it should add only a matter of seconds to the exam.

Source:

Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.). *Disease of the Breast, 3rd Edition*. Philadelphia, PA: W.B. Saunders Co., 1986.



Slide Credit: Modified from the Mammatech Corporation, Gainville, FL. Used with permission.

SLIDE 247

The breasts are then palpated in the supine position. In this position, the breast tissue will move toward the clavicles. This slide demonstrates the perimeter of the breast. Remember that a fascial sheath encompasses the whole breast, starting at the second rib and extending to the latissimus dorsi muscle laterally, the lateral edge of the sternum medially, and the inframammary crease inferiorly. Since the second rib is difficult to palpate accurately, the exam extends to the clavicle. Rather than a circle, then, CBE encompasses a pentagon-shaped area.

Source:

Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.). *Disease of the Breast. 3rd Edition*. Philadelphia, PA: W.B. Saunders Co., 1986.



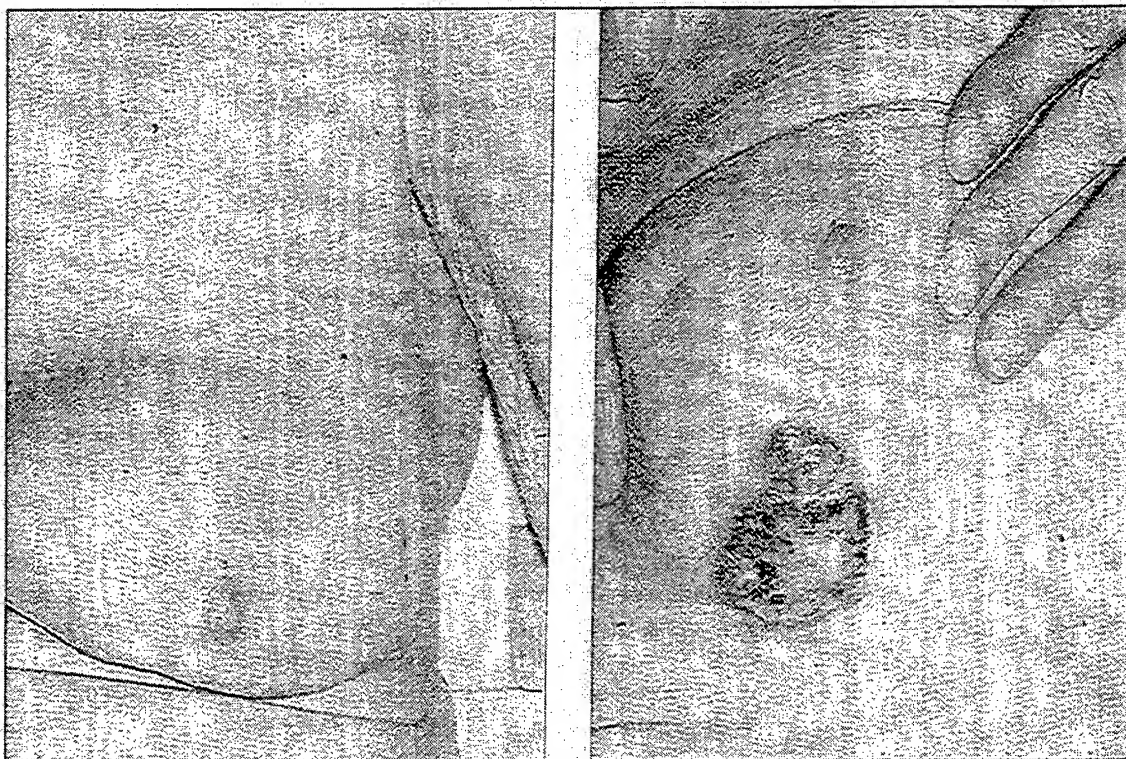
Slide Credit: from Haagensen CD, Bodian C, Haagensen DE (Eds.). *Breast Carcinoma: Risk and Detection*, Chapter 21, figure 21-1. Philadelphia, PA: W.B. Saunders Company, 1981. Used with permission.

SLIDE 248

All patients should be examined with the ipsilateral arm over the head, as this maneuver spreads the breast tissue across the chest wall. If the breast continues to overlap the chest wall following this maneuver, the examiner should displace the medial portion of the ipsilateral breast toward the opposite side when examining the lateral portion of the breast. Alternatively, placing a pillow or towel underneath the patient's back and shoulders as shown in this slide will also help the breasts to fall medially against the chest wall so as to facilitate the exam. This maneuver adds time to the exam and is awkward for some, but manual medial displacement works very well as discussed above.

Source:

Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition*. Philadelphia, PA: W.B. Saunders Co., 1986.



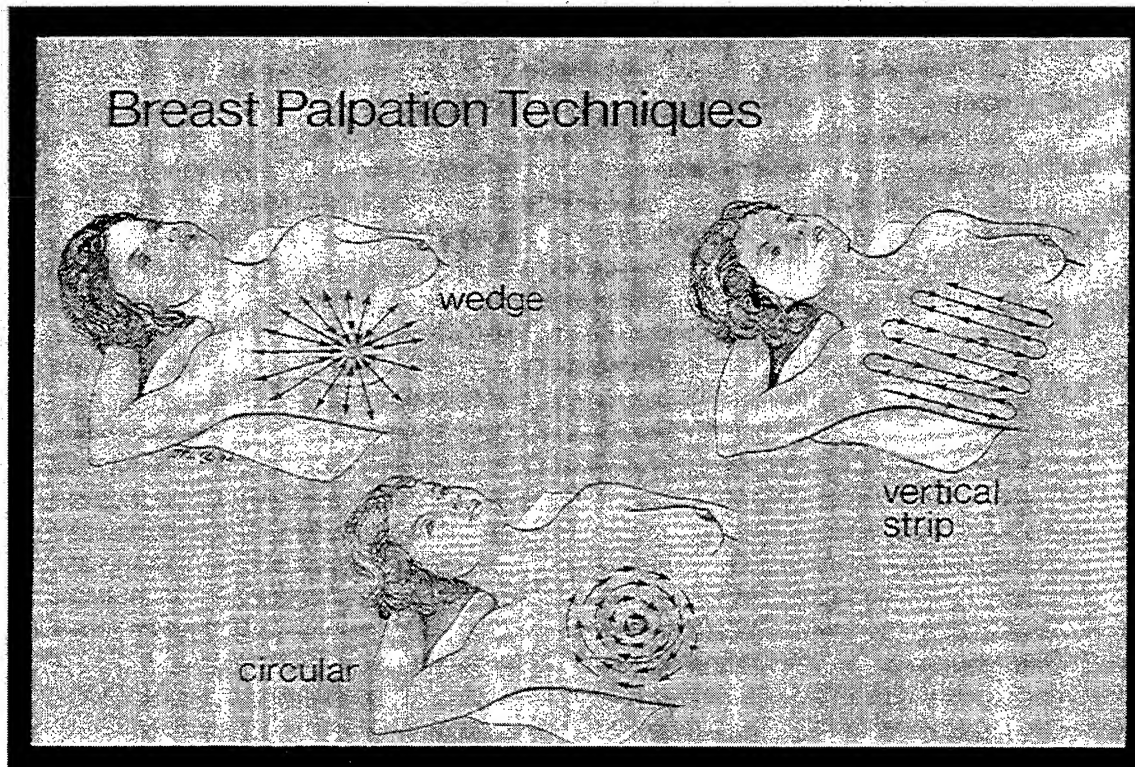
Slide Credit: from Mansel RE, Rundred NJ (Eds.), *Color Atlas of Breast Diseases*, Chapter 7, figure 7.9-7.10. London: Times Mirror International Publishers Limited, 1995. Used with permission.

SLIDE 249

The inspection portion of the examination should continue in the supine position for any portion of the breast not previously examined in the upright position. This typically involves examination of the inframammary fold, especially in women with pendulous breasts. It is easy to imagine how a lesion as large as this one would be missed without proper maneuvers of inspection.

Source:

Mansel RE, Rundred NJ (Eds). *Color Atlas of Breast Diseases*. London: Mosby-Wolfe. 1995.



Slide Credit: Slide No. 98 from Osuch JR, Dell DL, Sleighter S. *Breast and Cervical Cancer Education for Primary Care Providers*. Alexandria, VA: American Medical Women's Association, 1994, Joyce Lavery, MFA, CMI. Used with permission.

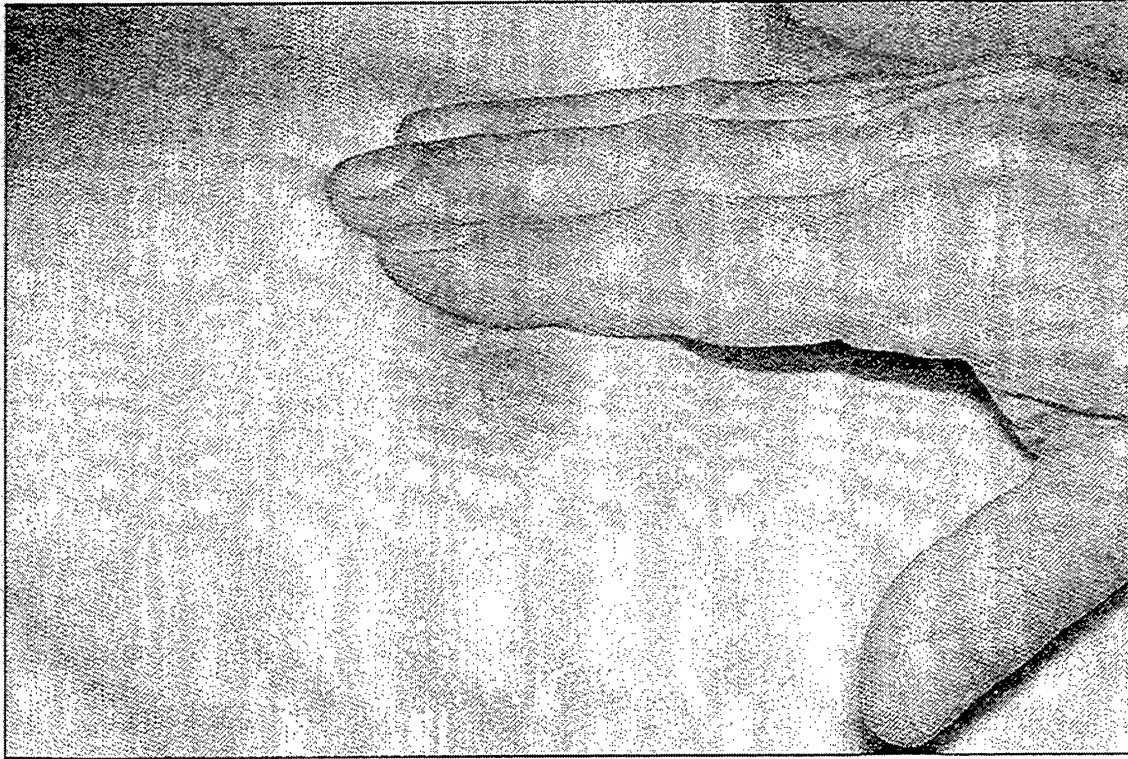
SLIDE 250

There are three techniques for breast palpation: circular, vertical strip, and wedge.

Any of these methods are appropriate as long as the entire pentagon-shaped area of the breast is examined.

Sources:

1. Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.). *Disease of the Breast, 3rd Edition*. Philadelphia, PA: W.B. Saunders Co., 1986.
2. Barton MB, Harris R, Fletcher SW. Does this patient have breast cancer? The screening clinical breast examination: should it be done? How? *JAMA* 1999; 282:1270-1280.



Slide Credit: from Blamey R, Evans A, Ellis I, et al. (Eds.). *Atlas of Breast Cancer*. Figure 9. . .
Hampshire, UK: Merit Publishing International, 1994. Used with permission.

SLIDE 251

When palpating the breast, the pads of the first three fingers are used, covering an area about the size of a dime for each examining finger. The depth of palpation is done first with a light touch, then a medium, and a deep in order to examine the breasts completely. The breasts are systematically examined in overlapping fields (like mowing a lawn). The least examined portion of the breast is the retro-areolar area. It is often believed that palpation of this area will be painful. This is not the case, however. This region is the second most likely to develop breast cancer and it is important that the breast be examined all the way to the nipple.

Sources:

1. Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.). *Disease of the Breast, 3rd Edition*. Philadelphia, PA: W.B. Saunders Co., 1986.
2. Barton MB, Harris R, Fletcher SW. Does this patient have breast cancer? The screening clinical breast examination: should it be done? How? *JAMA* 1999; 282:1270-1280.

Clinical Skills - CBE

- **Background nodularity**
- **Dominant mass/thickening**
- **Nipple compression with spontaneous nipple discharge**

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 1999.

SLIDE 252

When palpating the breast, assess the degree of nodularity and whether there is a dominant mass or thickening in the breast. Palpation of the nipple in a woman who does not have a history of persistent spontaneous nipple discharge is not recommended. Many physicians are surprised by this, as we have emphasized the importance of nipple compression to women performing BSE. Many needless work ups are prompted by the elicitation of nipple discharge that is not spontaneous. Remember that non-spontaneous nipple discharge is physiologic. CBE techniques in the presence of spontaneous discharge will be reviewed in an upcoming slide.

Source:

Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.). *Disease of the Breast, 3rd Edition*. Philadelphia, PA: W.B. Saunders Co., 1986.



Slide Credit: American Cancer Society, Atlanta, GA., Public Domain

SLIDE 253

When assessing nodularity and tissue thickening, it is helpful to examine the symmetry between the two breasts. Subtle thickenings and ridges felt on palpation of one breast can be compared to the opposite breast in the mirror image location, to determine if there is symmetrical thickening or nodularity in the opposite breast. If the exam is symmetrical, this is usually an indication that the exam is normal. If there is asymmetry, even if only a thickened area, further work up is necessary. Note that the exam for symmetry need not be done from the head of the table.

Source:

Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition*. Philadelphia, PA: W.B. Saunders Co., 1986.



Slide Credit: American Cancer Society, Atlanta, GA., Public Domain

SLIDE 254

In women with a history of persistent spontaneous nipple discharge, the nipple is compressed very gently in the horizontal and vertical directions to check for discharge. If this technique does not elicit the discharge, firm pressure should be applied from the periphery toward the nipple. Pressure should be distributed evenly so that the duct system is milked for each number on the clock.

Source:

Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition*. Philadelphia, PA: W.B. Saunders Co., 1986.

Clinical Skills - CBE

- Positions
- Palpation
 - Perimeter
 - Pattern of search
 - Palpation with pads
 - Pressure
- Patient education

Slide Credit: Osuch JR, Pathak DR, Barry HC, Zuber TJ. Michigan State University, 2000.

SLIDE 255

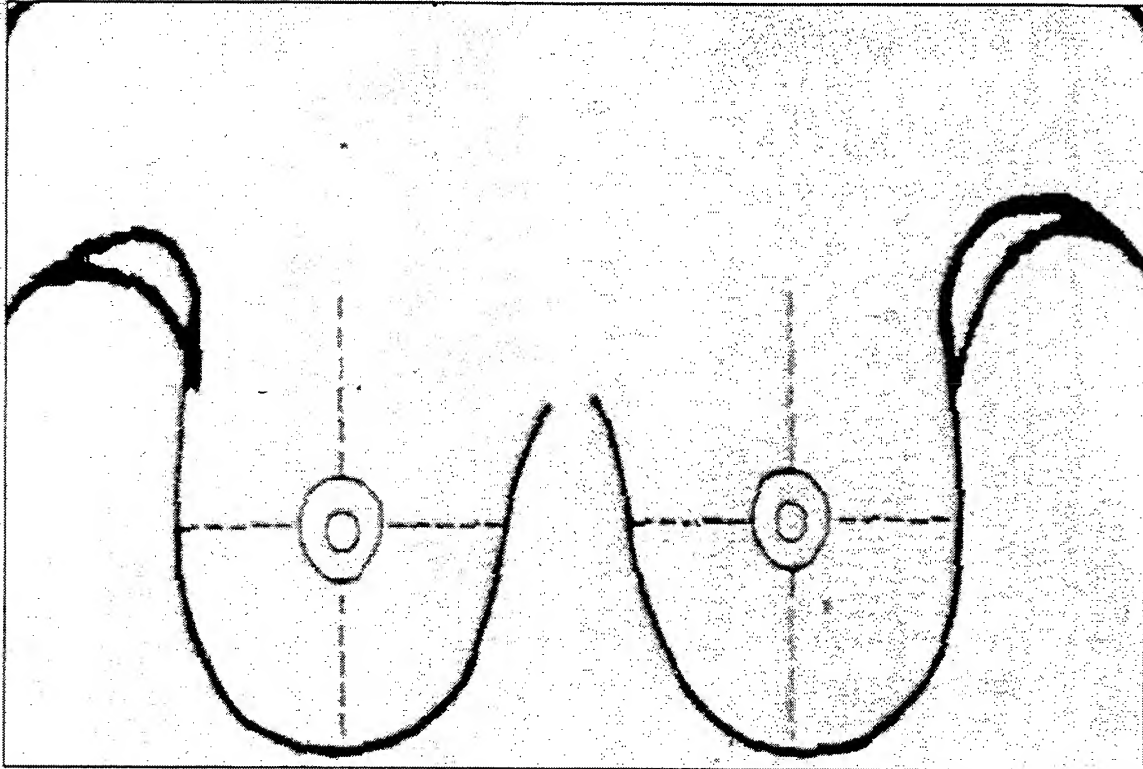
The steps in breast examination can be thought of in terms of seven P's. This includes:

- Positions
- Palpation
 - Perimeter
 - Pattern of search
 - Palpation with pads
 - Pressure
- Patient education

Appendix 8 lists a step-by-step approach to CBE using these seven P's.

Source:

Modified from Clinical Breast Examination: Proficiency Criteria and Guidelines. American Cancer Society, California Division. (Reprinted with permission)



Slide Credit: Drawing courtesy of the Comprehensive Breast Health Clinic, Michigan State University, East Lansing, MI.

SLIDE 256

Documentation is an extremely important part of the clinical breast examination. This is an example of a pre-printed form, but drawing two circles will suffice. We will now watch a video tape and observe CBE in real time.

Source for Videotape:

California Department of Health Services, 1996.

APPENDICES

1. Screening Guidelines for Women in Different Risk Categories
2. ANDI Classification
3. Management of Breast Pain
4. Management of Occult Mammographic Abnormalities
- 5A. Management of Initial Evaluation of a Breast Mass
- 5B. Management of a Breast Cyst
- 5C. Management of a Solid Breast Mass by Triple Diagnosis
6. Management of Nipple Discharge
7. Management of Observational Findings
8. Clinical Breast Exam: A Step-by-Step Approach
9. Common Allegations for Failure to Diagnose Breast Cancer and Recommended Steps in Risk Management
10. Instructions for Access to Medscape
11. Patient Risk Assessment Form
12. The Use of the Gail Model. Risk Assessment Tools-Practice Session

APPENDIX 1

SCREENING GUIDELINES FOR WOMEN IN DIFFERENT RISK CATEGORIES:

Risk Category	Lifetime Risk (%)	Clinical Breast Exam Schedule	Mammogram Schedule
No risk factors	11-12	Annual at and after age 30	Annual at and after age 40
<u>Two or more reproductive or hormonal risk factors and no family history</u>	10-20		
<u>Weak family history</u> (one first-degree relative with postmenopausal breast cancer, or one or two more distant relatives with postmenopausal breast cancer)	15-20		
<u>Strong family history</u> (three or more relatives at any age with postmenopausal breast cancer, or any second-degree relative with breast cancer before age 40)	> 20	Annual at and after age 25; Twice yearly after age 30	Annual at and after age 35 or 5 years younger than youngest affected relative
<u>Carrier of known breast cancer susceptibility gene</u> Or <u>Very strong family history</u> (two or more first degree relatives with breast or ovarian cancer, one or more first degree relatives with breast cancer before age 40, or any first degree relative with bilateral premenopausal breast cancer)	20-85	Twice yearly at and after age 25	Annual at and after age 25
<u>Atypical hyperplasia with a negative family history</u>	15-20	Annual at and after diagnosis	Age 40 or after diagnosis if earlier than age 40
<u>Atypical hyperplasia with a positive family history</u>	> 20	Twice yearly	
<u>Lobular carcinoma in situ</u>	20-30		

Modified after Garber JE and Smith BL. Management of the high-risk and the concerned patient. Table 9-3, page 329. In: Harris JR, Lippman ME, Morrow M, and Hillman S. *Diseases of the Breast*. Philadelphia, PA: Lippincott-Raven Publishers, 1996.

APPENDIX 2

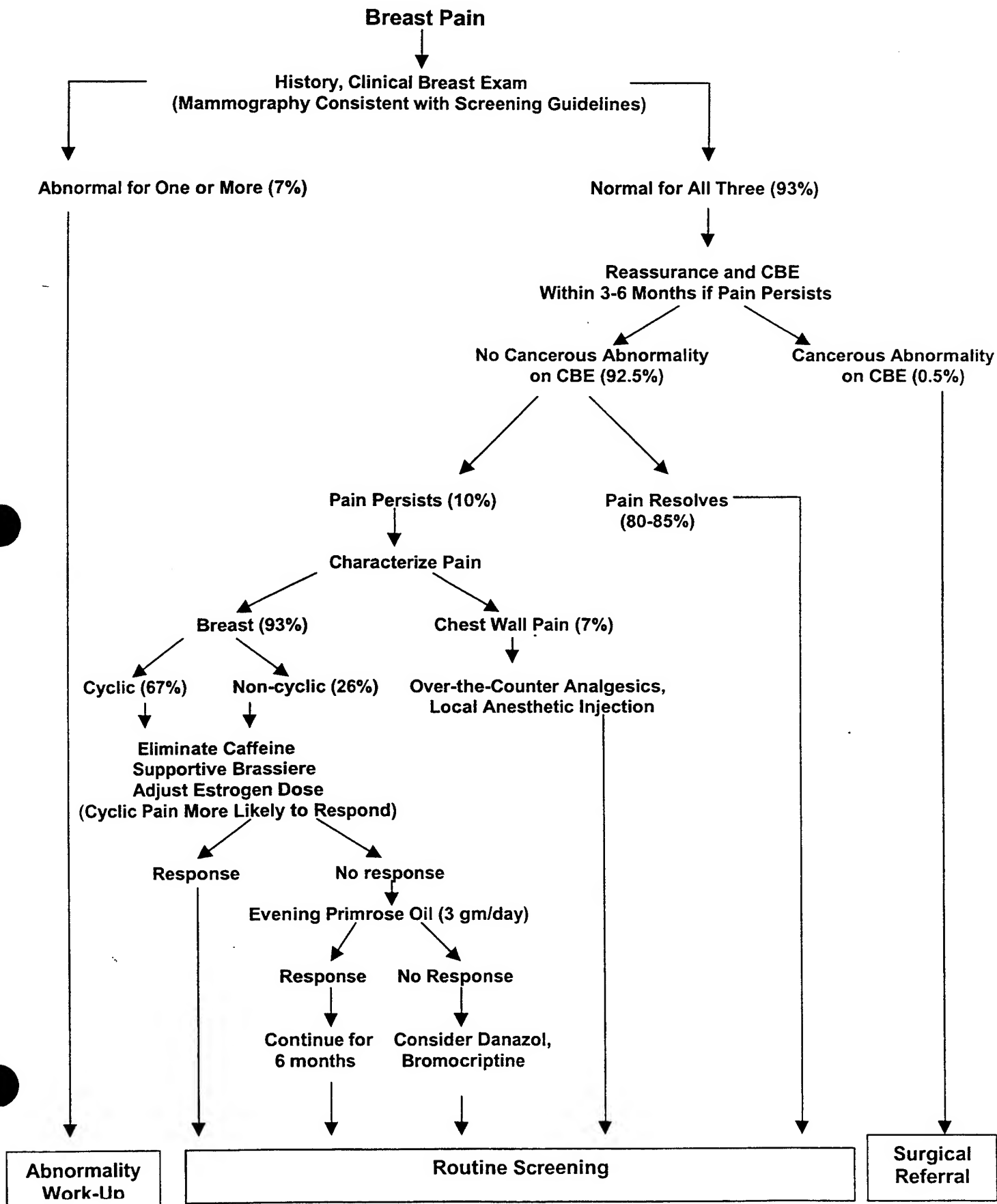
THE ANDI CLASSIFICATION OF BENIGN BREAST DISEASE

Stage (Peak Age)	Normal Process	Aberration		
		Underlying Condition	Clinical Presentation	Disease State
Early reproductive period (15-25 yr)	Lobule formation	Fibroadenoma	Discrete lump	Giant fibroadenoma
	Stroma formation	Juvenile Hypertrophy	Excessive breast development	Multiple fibroadenomas
Mature reproductive period (25-40 yr)	Cyclic hormonal effects on glandular tissue and stroma	Exaggerated cyclic effects	Cyclic mastalgia and nodularity, generalized or discrete	
Involution (35-55 yr)	Lobular involution (including microcysts, apocrine change, fibrosis and adenosis)	Macrocysts	Mastalgia	Periductal mastitis with bacterial infection and abscess formation
		Sclerosing lesions	Lumps	
			Mammogram abnormalities	
	Ductal Involution (including periductal round cell infiltrates)	Duct dilation	Nipple discharge	
		Periductal fibrosis	Nipple retraction	
	Epithelial turnover	Mild epithelial hyperplasia	Histological report	Epithelial hyperplasia with atypia

Modified from Hughes LE. A Unifying Concept for Benign Disorder of the Breast: ANDI. In Donegan WL, Spratt JS (eds): Diseases of the Breast. Philadelphia: WB Saunders; 1995.

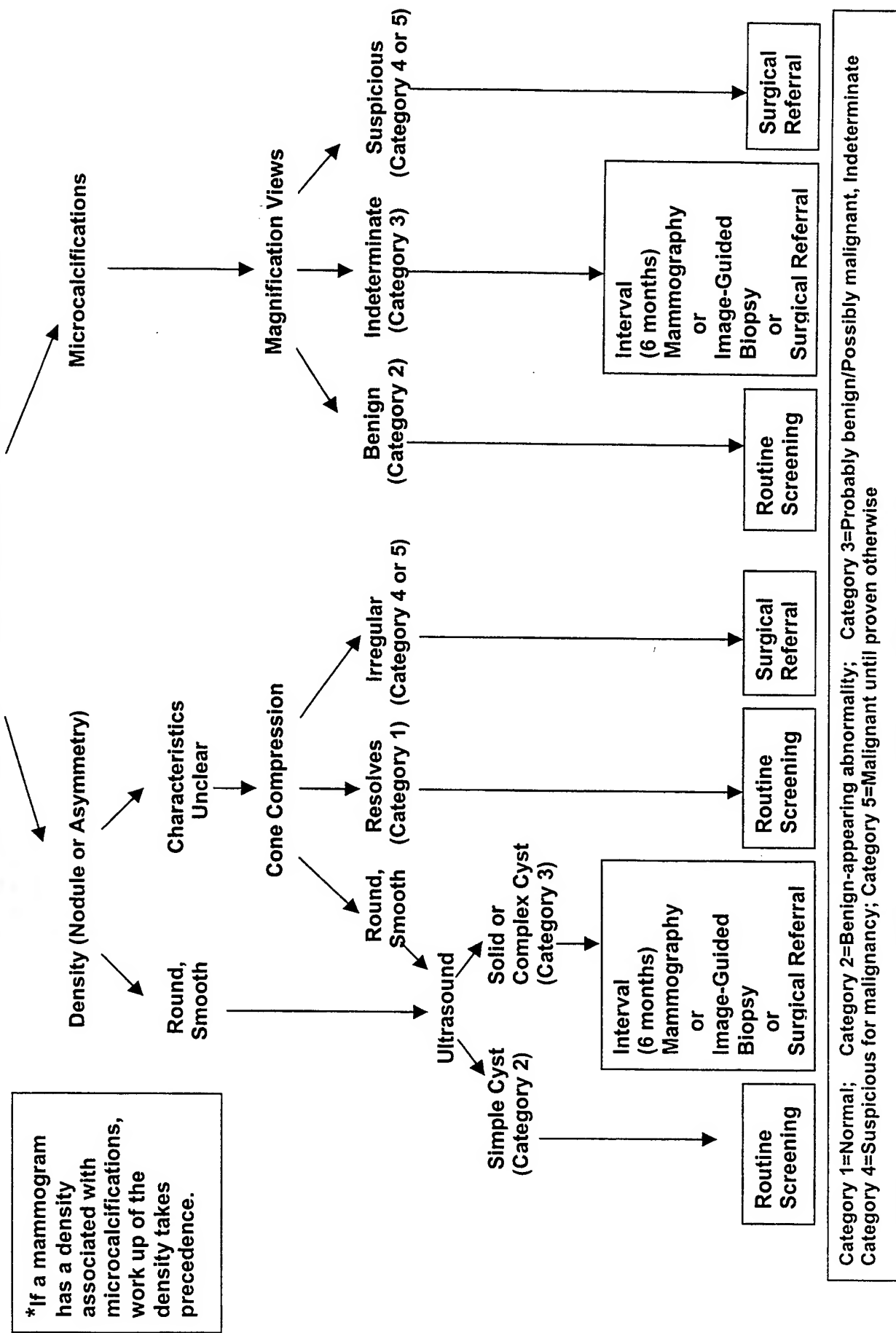
APPENDIX 3

MANAGEMENT OF BREAST PAIN



APPENDIX 4

MANAGEMENT OF OCCULT MAMMOGRAPHIC ABNORMALITY*

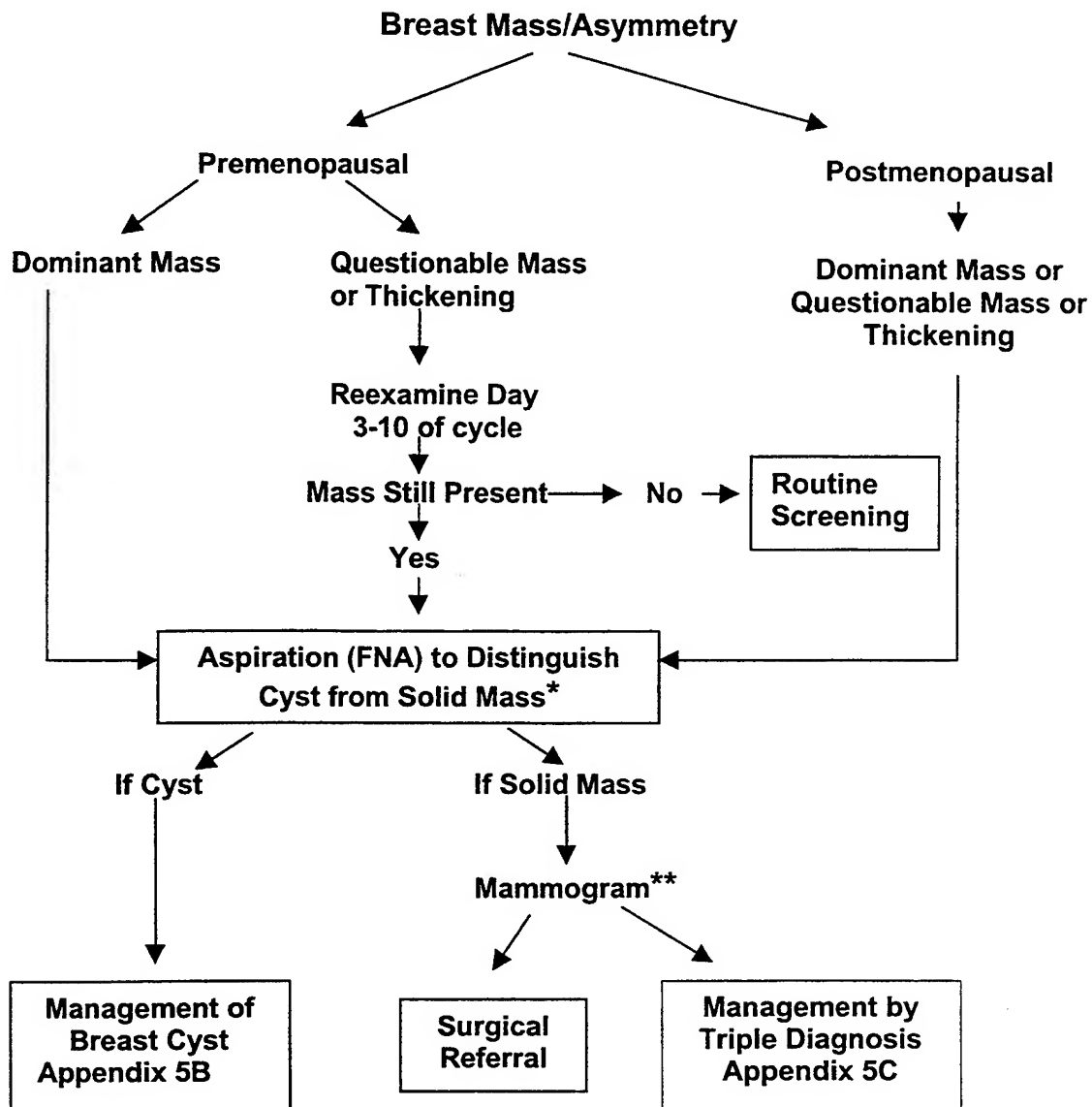


Modified from Morris LL and Osuch JR: Breast Cancer Education for Department of Defense Primary Care Managers. American Medical Women's Association. Alexandria, VA. 1998.

APPENDIX 5A

INITIAL APPROACH:

MANAGEMENT OF BREAST MASS/ASYMMETRY



*** Mammography**

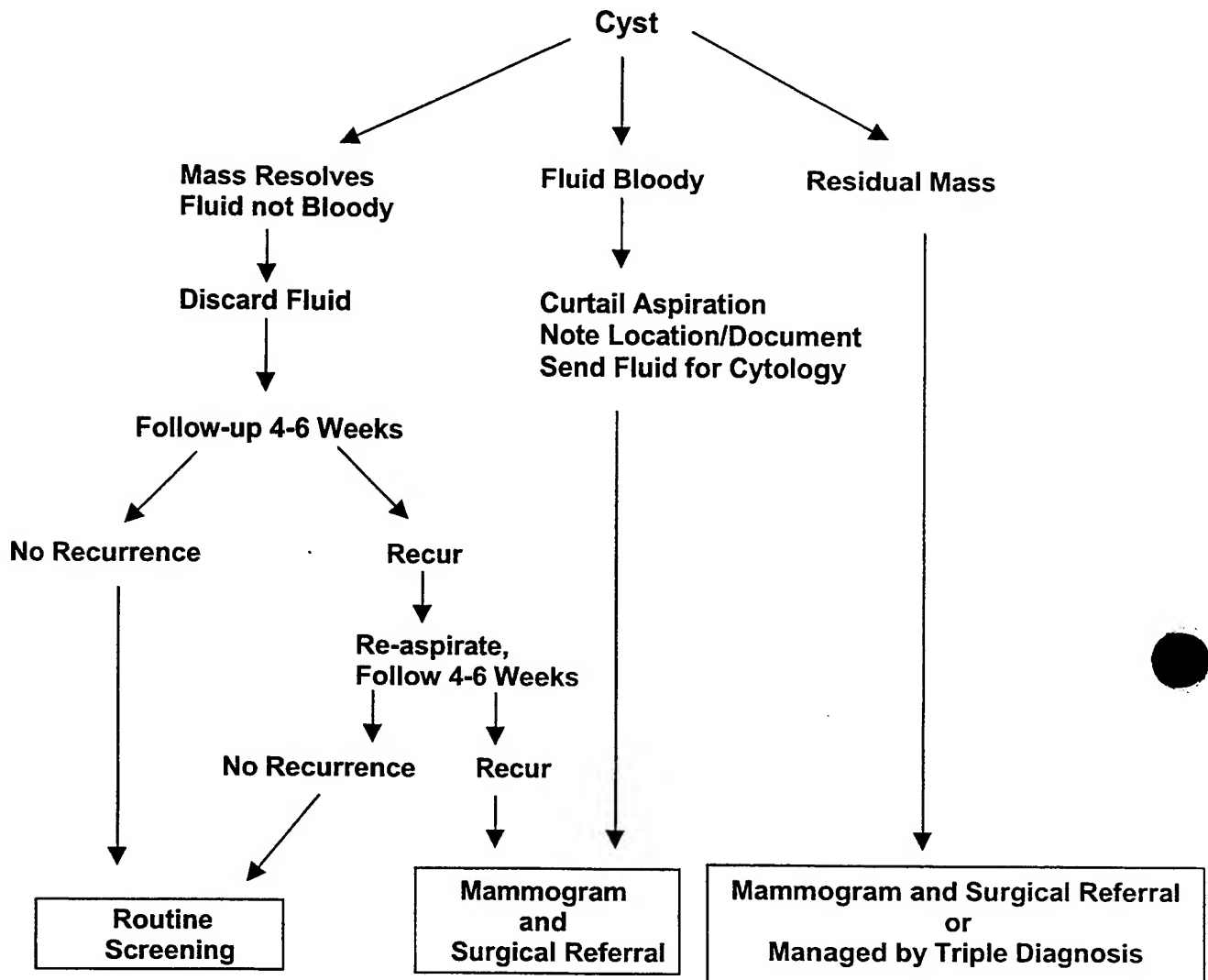
- a) could be done prior to Fine Needle Aspiration (FNA)
- b) should be avoided in women younger than 30 years old and pregnant women

**** Mammography should be ordered 2-3 weeks following aspiration to avoid false positive results.**

Modified from Osuch JR. Abnormalities on Physical Examination. In: Harris JR, Lippman ME, Morrow M, Hellman S, eds. Diseases of the Breast. Philadelphia: Lippincott-Raven, 1996:110-114. Reprinted with permission.

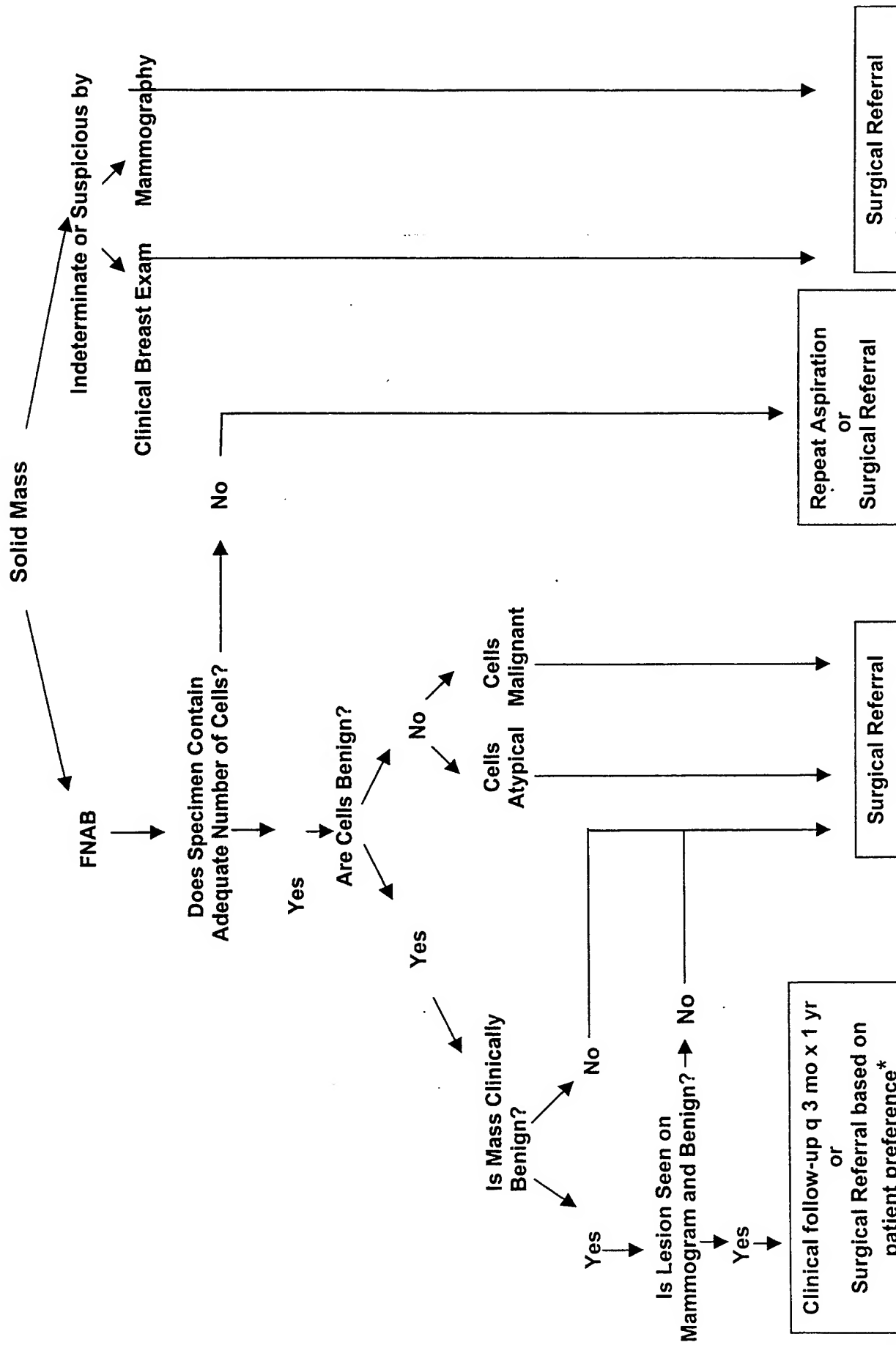
APPENDIX 5B

MANAGEMENT OF A BREAST CYST



Modified from: Osuch JR, Dell D, Sightler S. Breast and Cervical Cancer Education for Primary Care Providers. Alexandria, VA: American Medical Women's Association, 1994.

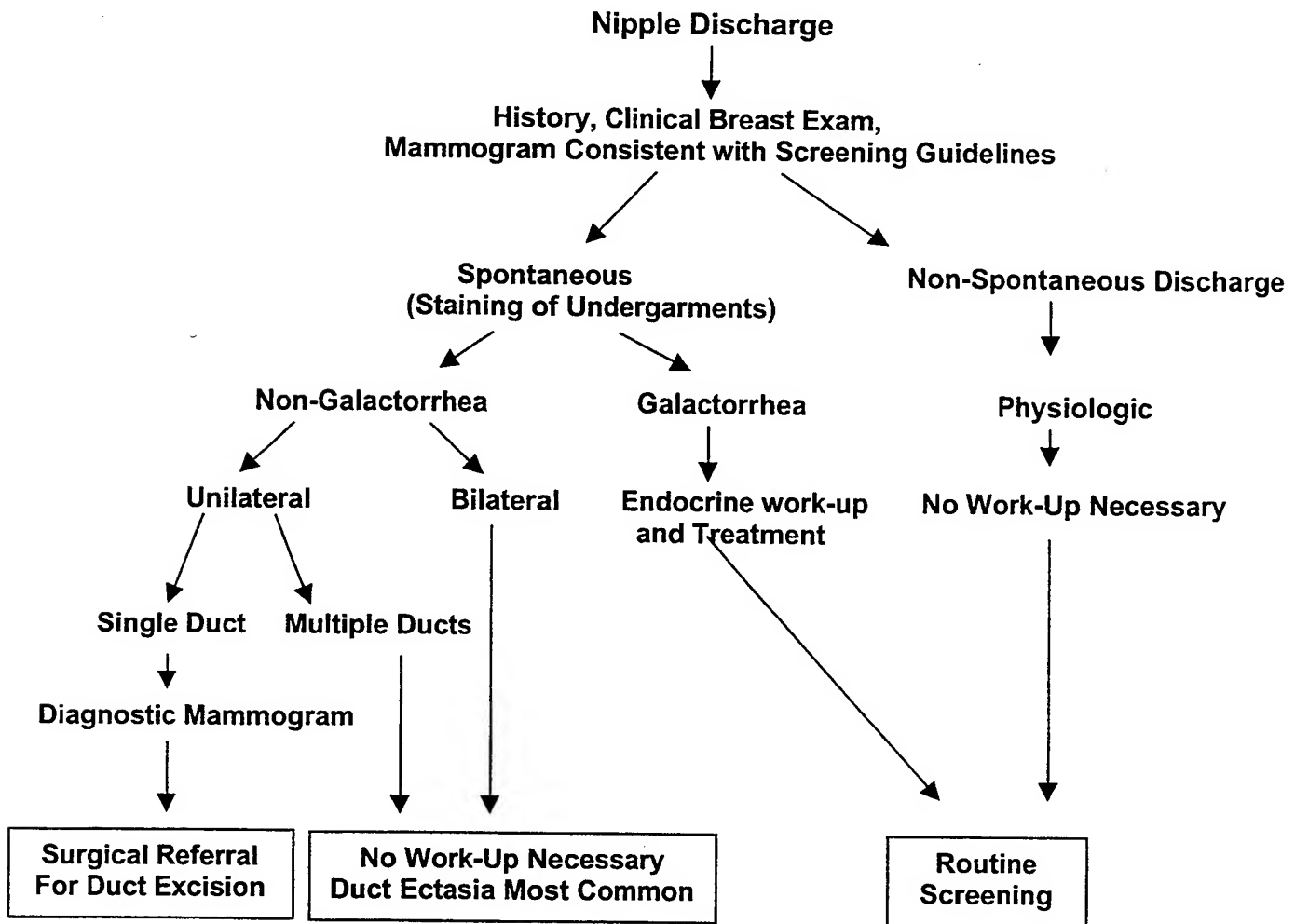
MANAGEMENT OF A SOLID MASS BY TRIPLE DIAGNOSIS



*All three elements must be benign. Cancer detected at follow-up in 1% of women.

APPENDIX 6

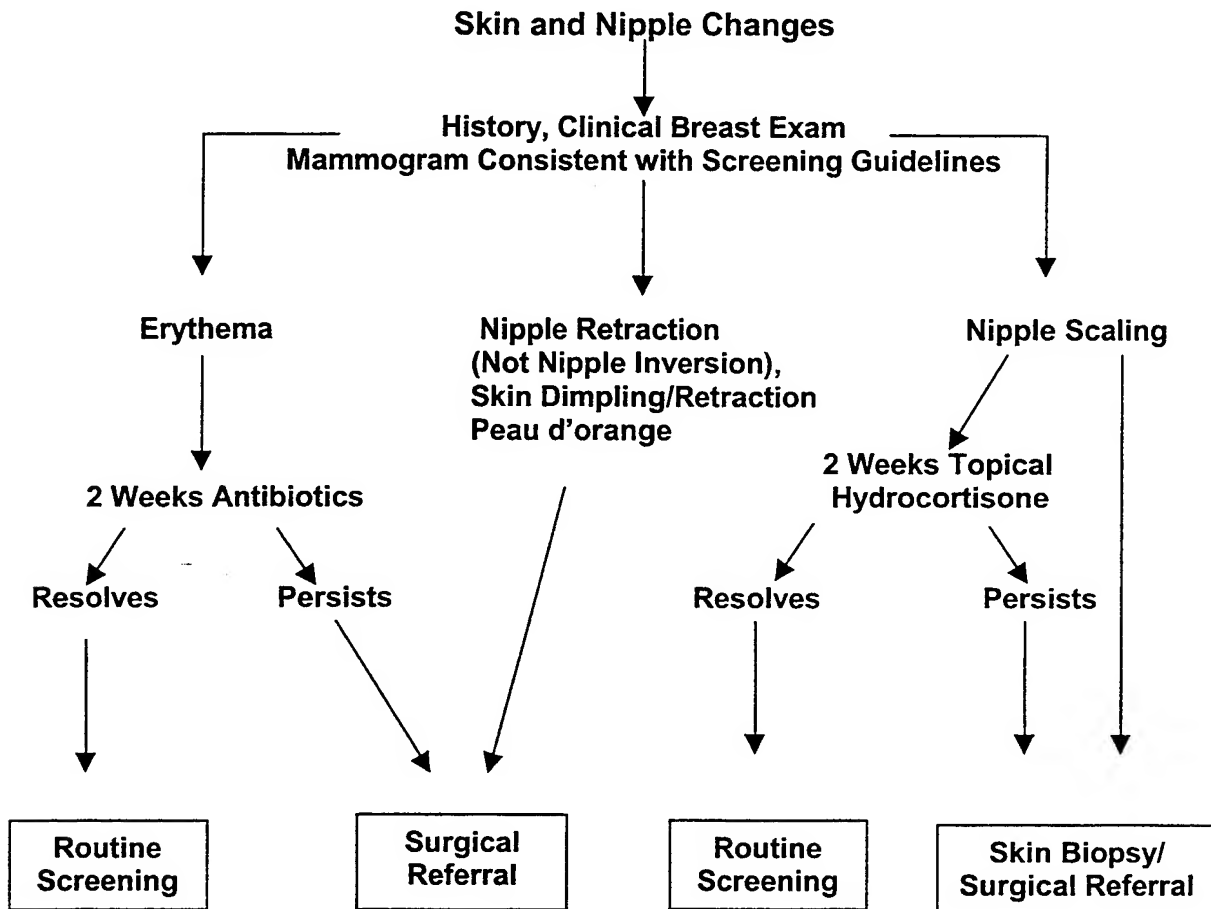
MANAGEMENT OF NIPPLE DISCHARGE



Modified from Morris LL and Osuch JR: Breast Cancer Education for Department of Defense Primary Care Managers. American Medical Women's Association. Alexandria, VA. 1998.

APPENDIX 7

MANAGEMENT OF SKIN AND NIPPLE CHANGES ON OBSERVATION



Modified from Morris LL and Osuch JR: Breast Cancer Education for Department of Defense Primary Care Managers. American Medical Women's Association. Alexandria, VA. 1998.

APPENDIX 8

CLINICAL BREAST EXAM: STEP-BY-STEP APPROACH

A Step-by-Step Approach

A useful approach to systematically perform CBE includes use of the "7 P's".

1. Ask patient to remove her gown. Visually inspect the breasts with the patient sitting and with arms at sides. Include frontal and lateral views. Look at SIZE, SHAPE, SYMMETRY, COLOR, TEXTURE, CONDITION OF NIPPLES (**POSITION**).
2. Repeat step 1 with arms overhead (**POSITION**).
3. Repeat step 1 with hands on hips, contracting pectoralis major. Look especially for skin dimpling with this maneuver (**POSITION**).
4. Palpate axillary and supraclavicular and infraclavicular lymph nodes with patient sitting (**POSITION, PALPATION**).
5. Help patient lie supine. Cover breast not being examined. Place ipsilateral arm overhead (**POSITION**).
6. Examine from ipsilateral side of table (**POSITION**).
7. Centralize the breast (manually or with a towel under the shoulder) (**POSITION**).
8. Visualize the perimeter of the breast (**PERIMETER**).
9. Choose a pattern of search. This should be either vertical strip, radial, or circular. Note that the circular method does not always cover the entire perimeter of the breast unless a conscious effort is made to do so. (**PATTERN OF SEARCH**).
10. Use pads of 3 middle fingers and examine in overlapping dime-sized circles (**PADS/PALPATION**).
11. Palpate the entire breast using the appropriate palpation techniques and sequential depths of pressure; light, medium and deep (**PALPATION, PRESSURE**).
12. During the process, the patient should be asked (**PATIENT EDUCATION**)
 - a. if she is comfortable
 - b. if the pressure is causing any discomfort
 - c. if she performs BSE, how often, and her level of confidence
 - d. if she has any questions or concerns
13. Emphasize to the patient the importance of the triad of Clinical Breast Examination, Breast Self Examination, and Mammography for early detection of breast problems (**PATIENT EDUCATION**).

Source: Osuch JR, Bonham VL, Morris LL. *Primary Care to Managing A Breast Mass: Step-by-Step Work Up*. Medscape Women's Health, 1998; Vol 3. No.5. <http://www.medscape.com> (See instructions in Appendix 10).

American Cancer Society, California Division-Clinical Breast Exam: Proficiency Criteria and Guideline, February 1988.

APPENDIX 9

COMMON ALLEGATIONS FOR FAILURE TO DIAGNOSE BREAST CANCER AND RECOMMENDED STEPS IN RISK MANAGEMENT

Allegation	Recommendation for risk management
<ul style="list-style-type: none"> • Failure to screen 	<ul style="list-style-type: none"> • Perform clinical breast exam according to guidelines • Order mammography according to guidelines • Teach patients breast self exam • Communicate recommendations • Document each step above
<ul style="list-style-type: none"> • Failure to have knowledge of abnormal mammogram results 	<ul style="list-style-type: none"> • Track results of tests • Communicate abnormal results and recommendations to patient • Document each step above
<ul style="list-style-type: none"> • Failure to follow up on complaint; failure to take patient complaint seriously 	<ul style="list-style-type: none"> • Perform focused history and clinical breast exam • Follow complaint to resolution or refer • Communicate findings/recommendations • Track patient follow-up appointments • Document each step above
<ul style="list-style-type: none"> • Failure to verify a patient complaint on physical exam 	<ul style="list-style-type: none"> • Perform careful history and clinical breast exam • Compare and confirm results of clinical breast exam with results of breast self-exam. • Repeat exam at best phase of menstrual cycle if ovulating • Follow complaint to resolution or refer • Communicate findings/recommendations • Track patient follow-up appointments • Document each step above
<ul style="list-style-type: none"> • Failure to follow up on a physical exam with abnormal findings 	<ul style="list-style-type: none"> • Follow physical finding to resolution or refer • Communicate findings/recommendations • Track patient follow-up appointments • If referred, establish follow-up responsibility with referring provider and patient • Document each step above
<ul style="list-style-type: none"> • Failure to refer 	<ul style="list-style-type: none"> • Refer any persistent breast abnormality to a specialist, no matter what the mammogram result • Communicate area of concern to patient and specialist • Establish follow-up responsibility • If surgical intervention deferred, establish clear follow-up plan • Document each step above

Modified from Osuch JR, Bonham VL. The timely diagnosis of breast cancer. *Cancer*. 1994;74:271-8.

APPENDIX 10

INSTRUCTION TO MEDSCAPE

To view the article, *Osuch JR, Bonham VL, and Morris LL. "Primary Care Guide to Managing a Breast Mass: Step-by-Step Workup* first sign in as described below in 1 and 2, then proceed using either Option 1 or Option 2.

1. www.medscape.com
 2. If your objective is to view an article, you must register. There will be a box in the upper left hand corner with the selections "Register" and "Sign In" and "Search." Click on "Register" and follow the directions.
-

Option 1

3. On the left hand side you will see a column of selections. Scroll down until you see: **Women's Health**. Click on it.
4. Again, on the left hand side you will see columns with headings. Scroll down until you see **Journal Room**. Click on it.
5. You will come to a page with a variety of Journal names. Click on **Medscape Women's Health**.
6. You will be asked for your User ID and password. Enter the information you chose when you registered.
7. You will open to a variety of articles. Look for the above "Osuch" article, Vol. 3, No. 5.

OR

Option 2

3. Return to the homepage after you have registered and in the upper left hand box where you see the search option, type in "Osuch."
4. Click on "Sign in and remember password" or "Sign in and do not remember password." Click on either one and Dr. Osuch's articles will come up, from which you may pick the appropriate one.

Use as a guide:

www.medscape/Medscape/Womenshealth/journal/1998/vo3.n05/wh3026.osuc/wh3026.osuc-01.html.



APPENDIX 11

Patient Form on The Gail Model Risk Assessment for Breast Cancer: Risk Assessment and Considerations and Contraindications to Tamoxifen Use

Name: _____

Date: _____

1. Have you ever been diagnosed with invasive breast cancer, ductal carcinoma in-situ of the breast, or lobular carcinoma in-situ of the breast? yes* _____ no _____

* If answer is "yes", the calculations for risk do not apply. Skip questions 2 – 7 and complete the rest of the form.

2. RACE:

African-American/ Black

Asian

Caucasian/ White

Other

3. CURRENT AGE:

4. How old were you when you had your first period?

5. Have you ever had a child?

yes _____ no _____

- 5a. If "yes", how old were you when you had your first child?

6. Have your mother or any of your sisters or daughters been diagnosed with breast cancer? (Blood relatives only)

yes _____ no _____

- 6a. If "yes", how many of these have had breast cancer?

7. Have you ever had tissue removed from your breast (breast biopsy)?

yes _____ no _____

- 7a. If "yes", how many times have you had a biopsy?

- 7b. Did any of your biopsies show atypical hyperplasia?

yes _____ no _____

8. Are you taking "The Pill" or any form of hormone birth control such as shots or implanted devices?

yes _____ no _____

9. Do you plan to become pregnant within the next 5 years?

yes _____ no _____

10. Are you taking hormone replacement therapy for menopause?

yes _____ no _____

11. Have you had a hysterectomy (removal of womb or uterus)?

yes _____ no _____

12. Have you ever had a blood clot in the lung (pulmonary embolism) or in a major vein (deep-vein thrombosis)?

yes _____ no _____

13. Are you taking blood-thinners (anticoagulants, coumadin)?

yes _____ no _____

Patient Form on The Gail Model Risk Assessment for Breast Cancer:
Risk Assessment and Considerations and Contraindications to Tamoxifen Use

Name: PRACTICE PATIENT

Date: _____

1. Have you ever been diagnosed with invasive breast cancer, ductal carcinoma in-situ of the breast, or lobular carcinoma in-situ of the breast? yes* _____ no X

* If answer is "yes", the calculations for risk do not apply. Skip questions 2 – 7 and complete the rest of the form.

2. RACE:

- ☒ African-American/ Black
☐ Asian
☐ Caucasian/ White
☐ Other

3. CURRENT AGE:

51

4. How old were you when you had your first period?

12

5. Have you ever had a child?

yes X no _____

- 5a. If "yes", how old were you when you had your first child?

24

6. Have your mother or any of your sisters or daughters been diagnosed with breast cancer? (Blood relatives only)

yes X no _____

- 6a. If "yes", how many of these have had breast cancer?

1

7. Have you ever had tissue removed from your breast (breast biopsy)?

yes X no _____

- 7a. If "yes", how many times have you had a biopsy?

1

- 7b. Did any of your biopsies show atypical hyperplasia?

yes X no _____

8. Are you taking "The Pill" or any form of hormone birth control such as shots or implanted devices?

yes _____ no X

9. Do you plan to become pregnant within the next 5 years?

yes _____ no X

10. Are you taking hormone replacement therapy for menopause?

yes _____ no X

11. Have you had a hysterectomy (removal of womb or uterus)?

yes _____ no X

12. Have you ever had a blood clot in the lung (pulmonary embolism) or in a major vein (deep-vein thrombosis)?

yes _____ no X

13. Are you taking blood-thinners (anticoagulants, coumadin)?

yes _____ no X

***The Use of the
Gail Model Risk
Assessment Tool***

The Use of the Gail Model Risk Assessment Tool

1. The practice patient who you will be assessing is a 51-year old Black woman who has completed a patient form on risk assessment and considerations and contraindications to Tamoxifen use, which is attached.
2. Before approaching the patient in question, it is necessary to calculate the risk for a woman of similar age and race to the patient you will be assessing. *This is done solely for purposes of comparison.* The calculation represents the "average risk" of a woman of similar age and race to your patient with no other known risk factors for breast cancer.

Calculation of Risk for a 51 year old Black woman of average risk:

1. Press the "on" button on the Gail Model Risk Assessment Tool
2. Press B for Black race *.
3. Enter 51 for the age of the patient. Point out that the number at the left of the calculator's screen represents the question number as listed on the left-hand panel of the calculator.
4. Press the green enter button.
5. Enter 14 for age at first menses (this is standard for the calculation of average risk).
6. Press the green enter button.
7. Enter 18 for age of first live birth (this is standard for the calculation of average risk).
8. Press the green enter button.
9. Enter zero for the number of first-degree relatives with breast cancer.
10. Press the green enter button.
11. Enter zero for the number of previous breast biopsies.
12. Press the green enter button.
13. Press the blue result button.

RESULTS:

- The first number that appears represents the **5-year absolute risk** for an average risk woman of the race and age designated. The average-risk 51 year old black woman's 5-year absolute risk for breast cancer is **0.4%**.

Interpretation: Four of 1000, (or 0.4 of 100) 51-year old Black women will be diagnosed with invasive breast cancer over the next 5 years.

- The second number that appears to the right of the first a few seconds later represents the **lifetime absolute risk** for breast cancer for an average risk woman of the race and age designated. The average-risk 51-year-old black woman's absolute lifetime risk for breast cancer is **3.2%**.

Interpretation: Thirty-two of 1000 (or 3.2 of 100) average-risk 51 year-old Black women will be diagnosed with invasive breast cancer over a lifetime, assuming a life expectancy of 90 years.

- **Remember that:**

An average risk woman is one with no additional risk factors. The baseline entries for an average risk woman always include menarche at age 14, first delivery at age 18, no family history, and no breast biopsies. Calculations will vary, then, only by age and race.

3. After calculations have been done for an average-risk 51 year-old Black woman, you are ready to calculate the risk for your practice patient.

Calculation of Risk for the practice patient:

4. Use the attached "Patient form on risk assessment and considerations and contraindications to Tamoxifen use" to find the appropriate data for entry into the Risk Assessment Tool (next page).
5. Follow the same steps as for data entry for an average-risk woman, making it specific to the individual woman presented in the attached form.
6. After entering '1' for breast biopsy, press the "Y" to designate a finding of atypical epithelial hyperplasia.
7. Press the blue result button.

RESULTS:

- The first number that appears represents the **5-year absolute risk** for all 51 year-old Black women with the risk profile entered. The average 5-year absolute risk for breast cancer for the practice patient is **2.6%**.

Interpretation: Twenty-six of 1000 (or 2.6 of 100) 51-year old Black women with the risk factor profile entered will be diagnosed with invasive breast cancer over the next 5 years.

- The second number that appears to the right of the first a few seconds later represents **the lifetime absolute risk** for breast cancer for all 51 year-old Black women with the risk profile entered. The average lifetime absolute risk for breast cancer for the practice patient is **19.6%**.

Interpretation: One hundred ninety-six of 1000 (or 19.6 of 100) 51 year old Black women with the risk factor profile entered will be diagnosed with invasive breast cancer over a lifetime, assuming a life expectancy of 90 years.

RECORD THE 5-YEAR AND LIFETIME ABSOLUTE RISK RESULTS FOR THE PRACTICE PATIENT AND THE AVERAGE RISK WOMAN OF THE SAME AGE AND RACE IN THE MEDICAL RECORD FOR FUTURE REFERENCE!

- Remember the contraindications, risks and side effects of Tamoxifen use as a risk reduction agent for breast cancer.

Contraindications:

Medical contraindications include:

- Current anticoagulant therapy
- History of deep vein thrombosis
- History of pulmonary embolism
- History of stroke

Lifestyle contraindications include:

- Pregnancy
- Lactation
- Hormonal contraception
- Hormone replacement therapy

Side Effects* Include:

Statistically significant side effects include:

- Endometrial carcinoma in postmenopausal women with a uterus
- Pulmonary embolism
- Cataracts and need for cataract surgery

Reported side effects not measured for statistical significance:

- Hot flashes
- Vaginal discharge

Possible other side effects include:

- Venous thromboembolism
- Stroke

*Premenopausal women were less likely to experience side effects than postmenopausal women were.

Review of Indications:

The P-1 Trial assessed Tamoxifen use in women 35 and over with a 5-year absolute risk of 1.67% or above, or women 35 and over with a history of lobular carcinoma in-situ. It reduced breast cancer incidence in women at all levels of high risk, ranging from categories of less than or equal to 2% to greater than or equal to 5%. The average risk assessed in the trial was 3.2%.

Tamoxifen use is not indicated in average-risk women for breast cancer, nor is it indicated in every high-risk woman. However, after considering the contraindications and side effects, women at high risk should be offered the choice of taking Tamoxifen to reduce the risk of breast cancer.

The Use of the Gail Model Risk Assessment Tool **Additional Considerations:**

If none of the race designations are applicable:

1. Explain to the patient that the risk assessment tool does not apply to her race.
2. Offer her a calculated estimate of risk based on the highest risk that is used in the Gail model.
3. If she is comfortable with this, press the A button.
4. Explain that the patient's actual risk may be lower than the number calculated, or if the family history is especially strong, the actual risk could be higher.

The calculator is programmed to turn off automatically if not used continuously.

The "C" button will clear the previous entry for a given case. Pushing the "C" button again will clear the previous entry for that same patient. To correct or restart the data entry on a specific patient, it may be easier to simply press the "on" button twice. This will cancel all previously made entries and prepare the calculator for a new case.

**Consent to participate in a study:
Improved Follow-up of Breast Abnormalities Through Comprehensive
Breast Care in Women 40 to 70 Years of Age**

INTRODUCTION

The Departments of Family Practice, Epidemiology, and Surgery at Michigan State University (MSU) are working with the directors of the MSU Family Practice Residency Programs to develop a model curriculum in comprehensive breast care. The curriculum has been tested in other settings and now we want to evaluate its performance in a residency setting and assess if it performs better than the current educational approach. To accomplish this, your director has agreed to make this newly developed curriculum for primary care physicians a required component of your residency training. The curriculum is made up of formal lectures, videotapes, and "hands on" learning with silicone models and live models. Additionally, we will be providing chart reminders to assist you in your care of women over the age of 40. The total time for the initial training workshop is 8 hours and the reassessment takes 2 hours.

PROCEDURES

To assess the effectiveness of the educational program, we will administer tests before and after the training sessions. We will use specially trained live models to assess your ability to properly perform a clinical breast examination. We will also be abstracting medical records of women over age 40. The information we collect will be used to see how well the training program performed in residency setting.

CONFIDENTIALITY

In order to preserve your confidentiality, the data we collect will not have any personal identifiers, but only study identifiers so we can link the information over time. All data will be pooled with that of other learners participating in the study. Your privacy will be protected to the maximum extent allowable by law. If you wish, upon completion of the study and data analysis, a summary will be made available to you. If you wish to receive a copy of the results, please fill out a postcard with your name and address.

RISK OF PARTICIPATION

There are no physical risks associated with participation in this study. We do not intend to make your performance known to others. Some learners become anxious when formal evaluations are performed. Other than this, we know of no other discomfort you might experience due to participation in the study.

BENEFIT OF PARTICIPATION

The benefit to you is unclear. If this program is a more effective learning model than standard approaches then by participating in the training sessions, the project will benefit you directly by enhancing your knowledge and skills for comprehensive breast care. Additionally, your colleagues will derive benefit from its use in the future.

While you have no choice in participating in the training program (it is a requirement of your residency), you do have the choice of allowing us to use and analyze your test results along with those of your colleagues. You are being asked to give us permission to use this data for the purposes of study and dissemination to other medical educators. If you decide that we cannot use your data, you will still participate in the educational program. Your director will not be asked to influence your decision to participate. Your participation is voluntary.

If you have any questions about this study, please contact the principal investigator, Dorothy Pathak, Ph.D. at Michigan State University, 517-353-0772.

Your signature indicates that you voluntarily participate in the research component of this project. You allow us to use the assessment tools as the data for the project.

Signature _____

Date _____

Review of Research Records

It should be noted that representatives of the U.S. Army Medical Research and Materiel Command are eligible to review research records as a part of their responsibility to protect human subjects in research.

Consent.doc revised: June 26, 2000.

UCRIHS APPROVAL FOR
THIS project EXPIRES:

JUN 30 2001

SUBMIT RENEWAL APPLICATION
ONE MONTH PRIOR TO
ABOVE DATE TO CONTINUE

HOW TO DOCUMENT

- Many physicians believe that they instinctively know how to document a medical record appropriately, but in retrospect find they have failed to do so.
- The medical record becomes a guide for physician and for subsequent providers.
- To ensure quality of care and manage the risk of liability it is necessary to thoroughly document:
 - Patient's health history
 - Symptoms and complaints
 - Clinical examination
 - Clinical decision making

Breast Disorders can be classified into one of five signs or symptoms: (Slide 87)

- Breast Pain
- Breast Mass or Asymmetrical Thickening
- Nipple Discharge
- Skin and Nipple Changes on Observation
- Occult (non-palpable) Mammographic Abnormalities

A Focused history for each of these common presenting complaints has been discussed in the curriculum; the first four of these are summarized below.

- **Breast Pain (Slide 89)**
 - 1) Location
 - 2) Duration
 - 3) Unilateral/Bilateral
 - 4) Rank on 10-point scale
 - 5) Relation to hormones
 - 6) Lifestyle-altering
 - 7) Worry
- **Breast Mass or Asymmetrical Thickening (Slide 143)**
 - 1) Location
 - 2) Method of discovery
 - 3) Size
 - 4) Duration
 - 5) Hormonal influences
 - 6) Characteristics of tenderness
- **Nipple Discharge (Slide 170)**
 - 1) Spontaneous
 - 2) Color
 - 3) One duct/more than one
 - 4) Unilateral/bilateral
 - 5) Duration
 - 6) Persistent
- **Skin and Nipple Changes on Observation (Slide 182)**
 - 1) Location
 - 2) Date first noticed
 - 3) Have there been any changes since the date of symptom onset

DOCUMENTATION OF THE CLINICAL BREAST EXAM SHOULD INCLUDE MENTION OF:

- 1) Inspection
 - 2) Palpation
 - 3) Lymph node examination
- **Statement if findings are Normal vs Abnormal**
 - **IF ABNORMAL**
 - A basic diagram of the breast should be incorporated into the medical record using a prepared form or a simple drawing to document the location of patient's complaints and findings on CBE. Written documentation should specify:
 - **For Breast Pain**
 - 1) Breast vs Chest Wall Pain
 - 2) If Breast Pain -- Cyclic vs Non-cyclic
 - 3) *Document work-up to resolution or referral*
 - **Breast Mass or Asymmetrical Thickening**
 - 1) When the lump was detected
 - 2) Location and Size of lump
 - 3) Associated changes in the breast (eg, nipple discharge, nipple or breast skin abnormality, skin erythema, dimpling, pain)
 - 4) Patient's findings -- location of the lump or the change in the breast should be fully documented
 - 5) *Document work-up to resolution or referral*
 - **Nipple Discharge**
 - 1) Is there a history of spontaneous discharge
 - 2) Is it elicited on physical examination
 - 3) Is it from one or multiple ducts
 - 4) Location
 - 5) *Document work-up to resolution or referral*
 - **Skin and Nipple Changes on Observation**
 - 1) Congenital
 - 2) Nipple changes -- a)Scaling, b)Retraction
 - 3) Skin Changes -- a)Erythema, b)Dimpling, c) Retraction, d) Peau d'orange
 - 4) *Document work-up to resolution or referral.*

Occult (non-palpable) Mammographic Abnormalities - Document Initial Work-up (Slide 109)

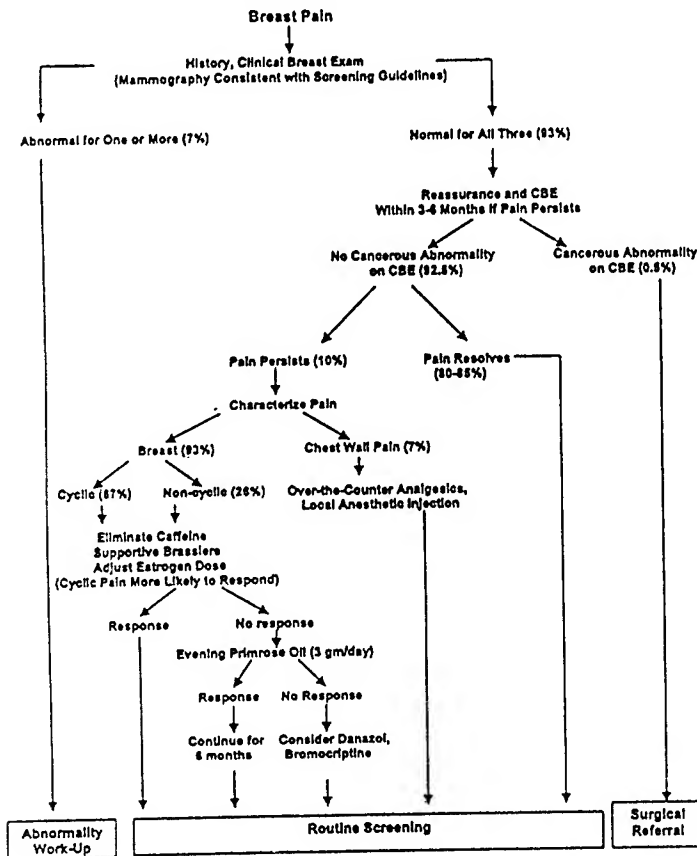
- 1) Had diagnostic mammogram been ordered -- a) Cone or Spot compression, b) Magnification
- 2) Had Ultrasound been ordered
- 3) *Document Work-up to resolution or referral.*

REMEMBER THE IMPORTANCE OF DOCUMENTING EVERY STEP IN THE CLINICAL DECISION PROCESS.

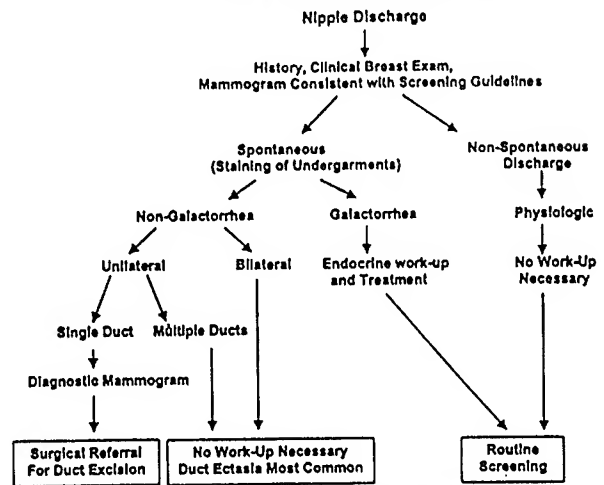
Modified from Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a breast Mass: A Legal Perspective on Risk Management. Medscape Women's Health, 1998: Vol 3.No.5.
<http://www.medscape.com> (see instructions in Appendix 10).

GUIDELINES FOR FOLLOW-UP OF BREAST ABNORMALITIES

MANAGEMENT OF BREAST PAIN

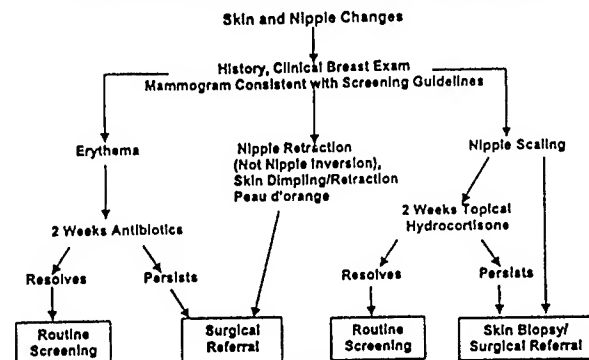


MANAGEMENT OF NIPPLE DISCHARGE



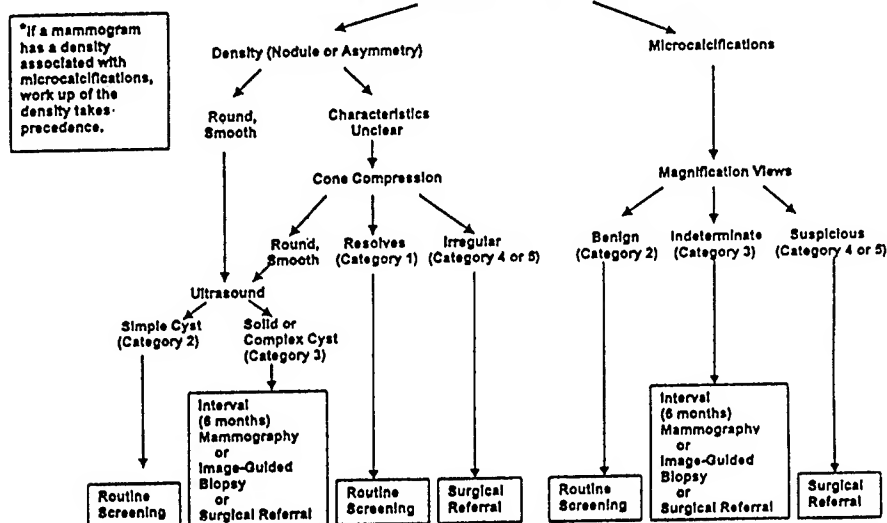
Modified from Morris LL and Osuch JR: Breast Cancer Education for Department of Defense Primary Care Managers. American Medical Women's Association. Alexandria, VA. 1998.

MANAGEMENT OF SKIN AND NIPPLE CHANGES ON OBSERVATION



Modified from Morris LL and Osuch JR: Breast Cancer Education for Department of Defense Primary Care Managers. American Medical Women's Association. Alexandria, VA. 1998.

MANAGEMENT OF OCCULT MAMMOGRAPHIC ABNORMALITY*



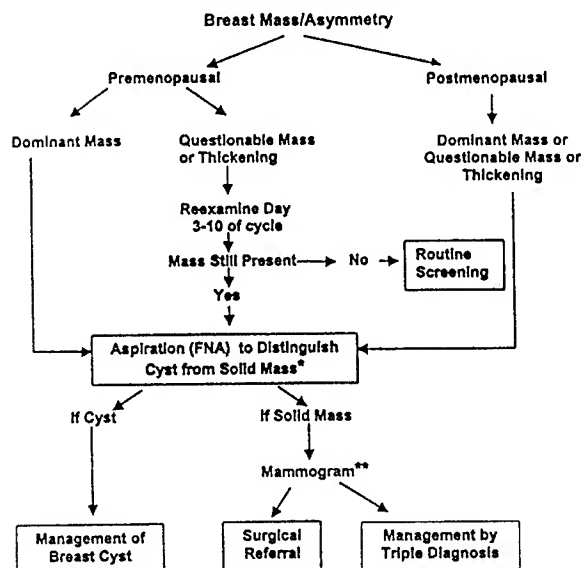
Category 1=Normal; Category 2=Benign-appearing abnormality; Category 3=Probably benign/Possibly malignant, Indeterminate; Category 4=Suspicious for malignancy; Category 5=Malignant until proven otherwise

Modified from Morris LL and Osuch JR: Breast Cancer Education for Department of Defense Primary Care Managers. American Medical Women's Association. Alexandria, VA. 1998.

GUIDELINES FOR FOLLOW-UP OF BREAST ABNORMALITIES

INITIAL APPROACH:

MANAGEMENT OF BREAST MASS/ASYMMETRICAL THICKENING



* Mammography

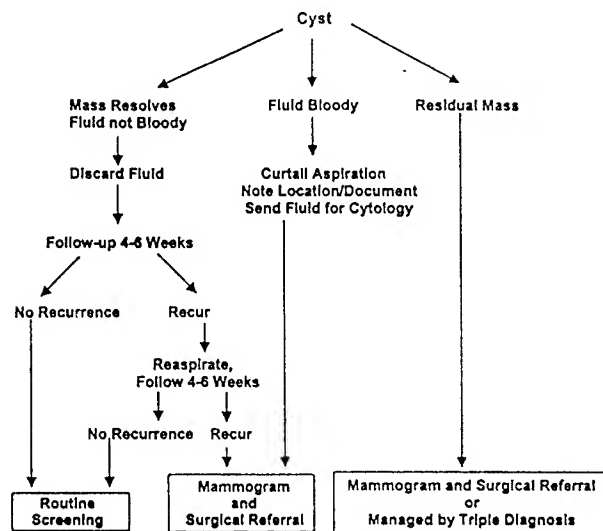
a) could be done prior to Fine Needle Aspiration (FNA)

b) should be avoided in women less than 30 years old and the pregnant women

** Mammography should be ordered 2-3 weeks following aspiration to avoid false positive results.

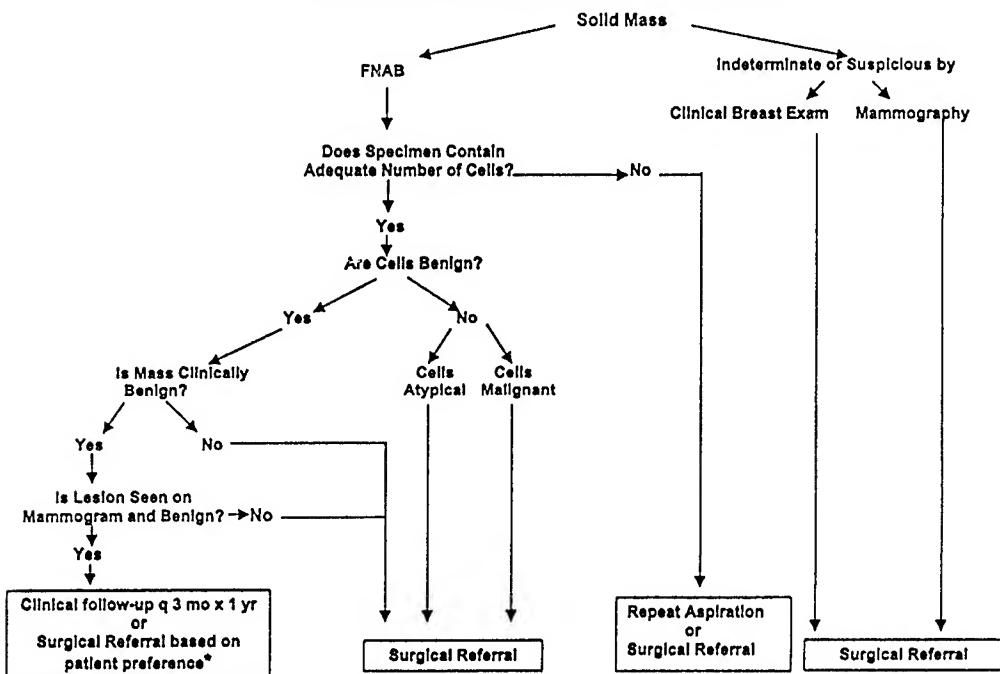
Modified from Osuch JR. Abnormalities on Physical Examination. In: Harris JR, Lippman ME, Morrow M, Hellman S, eds. *Diseases of the Breast*. Philadelphia: Lippincott-Raven, 1996:110-114. Reprinted with permission.

MANAGEMENT OF A BREAST CYST



Modified from: Osuch JR, Dell D, Sighler S. Breast and Cervical Cancer Education for Primary Care Providers. Alexandria, VA: American Medical Women's Association, 1994.

MANAGEMENT OF A SOLID MASS BY TRIPLE DIAGNOSIS



*All three elements must be benign. Cancer detected at follow-up in 1% of women.

Modified from Osuch JR. Abnormalities on Physical Examination. In: Harris JR, Lippman ME, Morrow M, Hellman S, eds. *Diseases of the Breast*. Philadelphia, PA: Lippincott-Raven, 1996:110-114. Reprinted with permission.

APPENDIX 3

Documentation of the Clinical Breast Examination

HOW TO DOCUMENT

- Many physicians believe that they instinctively know how to document a medical record appropriately, but in retrospect find they have failed to do so.
- The medical record becomes a guide for physician and for subsequent providers.
- To ensure quality of care and manage the risk of liability it is necessary to thoroughly document:
 - Patient's health history
 - Symptoms and complaints
 - Clinical examination
 - Clinical decision making

Breast Disorders can be classified into one of five signs or symptoms: (Slide 87)

- Breast Pain
- Breast Mass or Asymmetrical Thickening
- Nipple Discharge
- Skin and Nipple Changes on Observation
- Occult (non-palpable) Mammographic Abnormalities

A Focused history for each of these common presenting complaints has been discussed in the curriculum; the first four of these are summarized below.

- **Breast Pain (Slide 89)**
 - 1) Location
 - 2) Duration
 - 3) Unilateral/Bilateral
 - 4) Rank on 10-point scale
 - 5) Relation to hormones
 - 6) Lifestyle-altering
 - 7) Worry
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 - 1) Location
 - 2) Method of discovery
 - 3) Size
 - 4) Duration
 - 5) Hormonal influences
 - 6) Characteristics of tenderness
- **Nipple Discharge (Slide 170)**
 - 1) Spontaneous
 - 2) Color
 - 3) One duct/more than one
 - 4) Unilateral/bilateral
 - 5) Duration
 - 6) Persistent
- **Skin and Nipple Changes on Observation (Slide 182)**
 - 1) Location
 - 2) Date first noticed
 - 3) Have there been any changes since the date of symptom onset

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 - 2) Palpation
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 - 1) When the lump was detected
 - 2) Location and Size of lump
 - 3) Associated changes in the breast (eg, nipple discharge, nipple or breast skin abnormality, skin erythema, dimpling, pain)
 - 4) Patient's findings -- location of the lump or the change in the breast should be fully documented
 - 5) *Document work-up to resolution or referral*
 - **Nipple Discharge**
 - 1) Is there a history of spontaneous discharge
 - 2) Is it elicited on physical examination
 - 3) Is it from one or multiple ducts
 - 4) Location
 - 5) *Document work-up to resolution or referral*
 - **Skin and Nipple Changes on Observation**
 - 1) Congenital
 - 2) Nipple changes -- a)Scaling, b)Retraction
 - 3) Skin Changes -- a)Erythema, b)Dimpling, c) Retraction, d) Peau d'orange
 - 4) *Document work-up to resolution or referral.*
 - **Occult (non-palpable) Mammographic Abnormalities - Document Initial Work-up (Slide 109)**
 - 1) Had diagnostic mammogram been ordered -- a) Cone or Spot compression, b) Magnification
 - 2) Had Ultrasound been ordered
 - 3) *Document Work-up to resolution or referral.*

REMEMBER THE IMPORTANCE OF DOCUMENTING EVERY STEP IN THE CLINICAL DECISION PROCESS.

**Modified from Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a breast Mass: A Legal Perspective on Risk Management. Medscape Women's Health, 1998: Vol 3.No.5.
<http://www.medscape.com> (see instructions in Appendix 10).**

APPENDIX 4

Chart Reminder Guideline System

SUMMARY OF BREAST CARE

Last visit prior to edit __ / __ / __ End date for review (15 months) __ / __ / __

BREAST CARE:

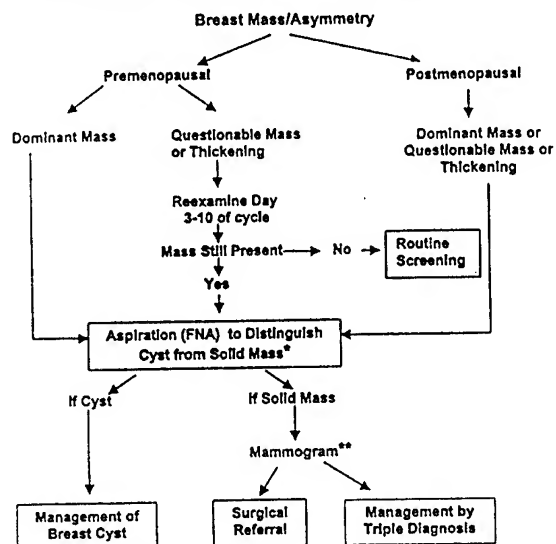
None during this time period _____

<u>Date:</u>	<u>Type of Breast Care</u>	<u>Codes for Type of Breast Care:</u>
__ / __ / __	_____	Normal CBE –N CBE
__ / __ / __	_____	Abnormal CBE – Abn CBE
__ / __ / __	_____	Lump
__ / __ / __	_____	Nipple Discharge
__ / __ / __	_____	Skin Changes
__ / __ / __	_____	Breast Pain
__ / __ / __	_____	Other
__ / __ / __	_____	Normal Mammogram –N Mammo
__ / __ / __	_____	Abnormal Mammogram--Abn Mammo
__ / __ / __	_____	Other Test results
__ / __ / __	_____	FNA
__ / __ / __	_____	FNAB
__ / __ / __	_____	Ultra Sound – U/S
__ / __ / __	_____	Surgeon's Letter –SL
__ / __ / __	_____	Biopsy report
__ / __ / __	_____	Other (specify)
__ / __ / __	_____	
__ / __ / __	_____	
__ / __ / __	_____	
__ / __ / __	_____	

GUIDELINES FOR FOLLOW-UP OF BREAST ABNORMALITIES

INITIAL APPROACH:

MANAGEMENT OF BREAST MASS/ASYMMETRICAL THICKENING



* Mammography

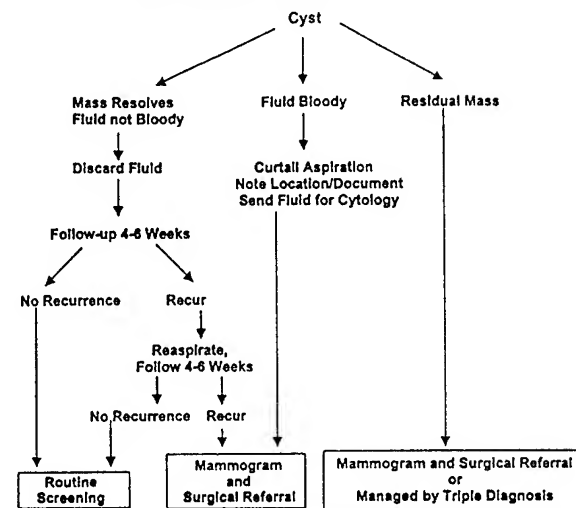
a) could be done prior to Fine Needle Aspiration (FNA)

b) should be avoided in women less than 30 years old and the pregnant women

** Mammography should be ordered 2-3 weeks following aspiration to avoid false positive results.

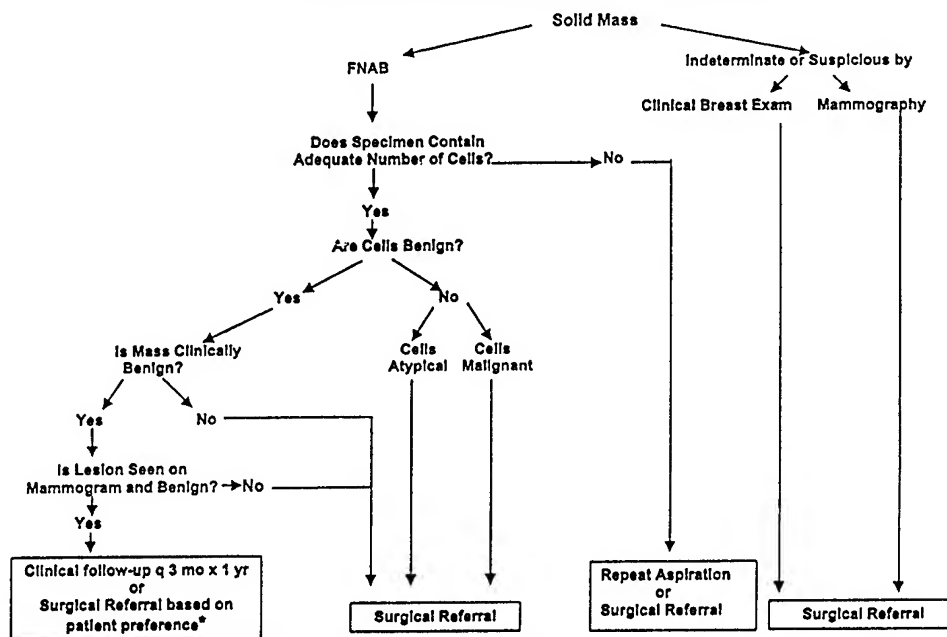
Modified from Osuch JR. Abnormalities on Physical Examination. In: Harris JR, Lippman ME, Morrow M, Hellman S, eds. Diseases of the Breast. Philadelphia: Lippincott-Raven, 1996:110-114. Reprinted with permission.

MANAGEMENT OF A BREAST CYST



Modified from: Osuch JR, Dell D, Slighter S. Breast and Cervical Cancer Education for Primary Care Providers. Alexandria, VA: American Medical Women's Association, 1994.

MANAGEMENT OF A SOLID MASS BY TRIPLE DIAGNOSIS

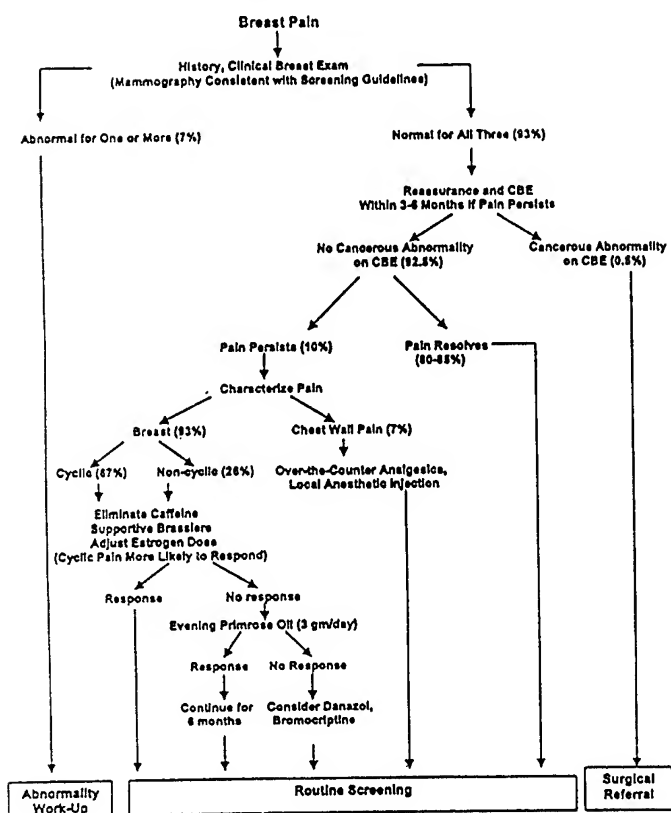


*All three elements must be benign. Cancer detected at follow-up in 1% of women.

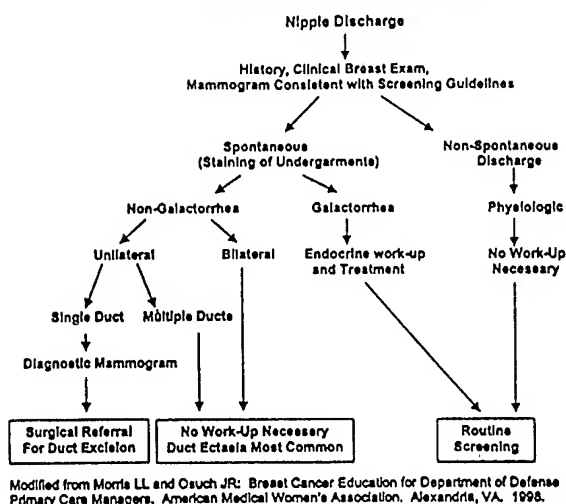
Modified from Osuch JR. Abnormalities on Physical Examination. In: Harris JR, Lippman ME, Morrow M, Hellman S, eds. Diseases of the Breast. Philadelphia, PA: Lippincott-Raven, 1996:110-114. Reprinted with permission.

GUIDELINES FOR FOLLOW-UP OF BREAST ABNORMALITIES

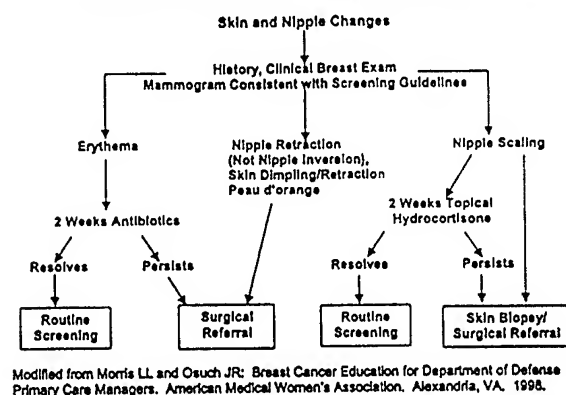
MANAGEMENT OF BREAST PAIN



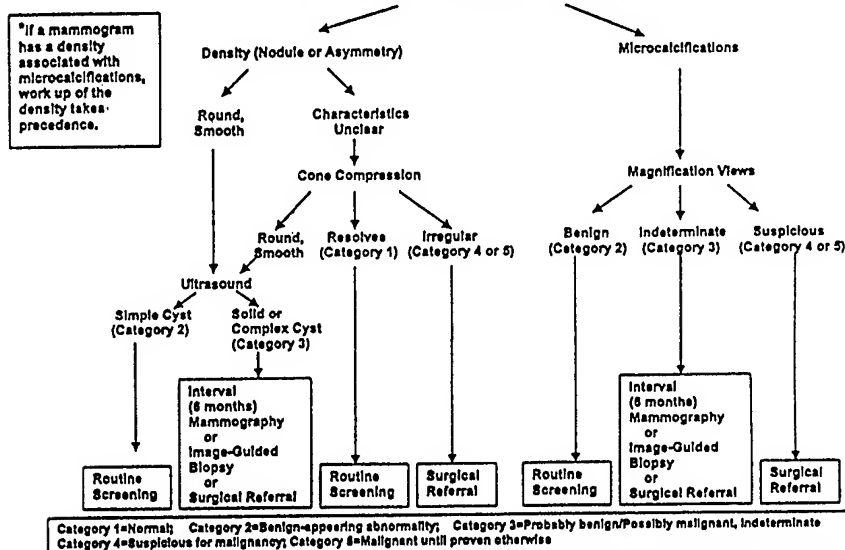
MANAGEMENT OF NIPPLE DISCHARGE

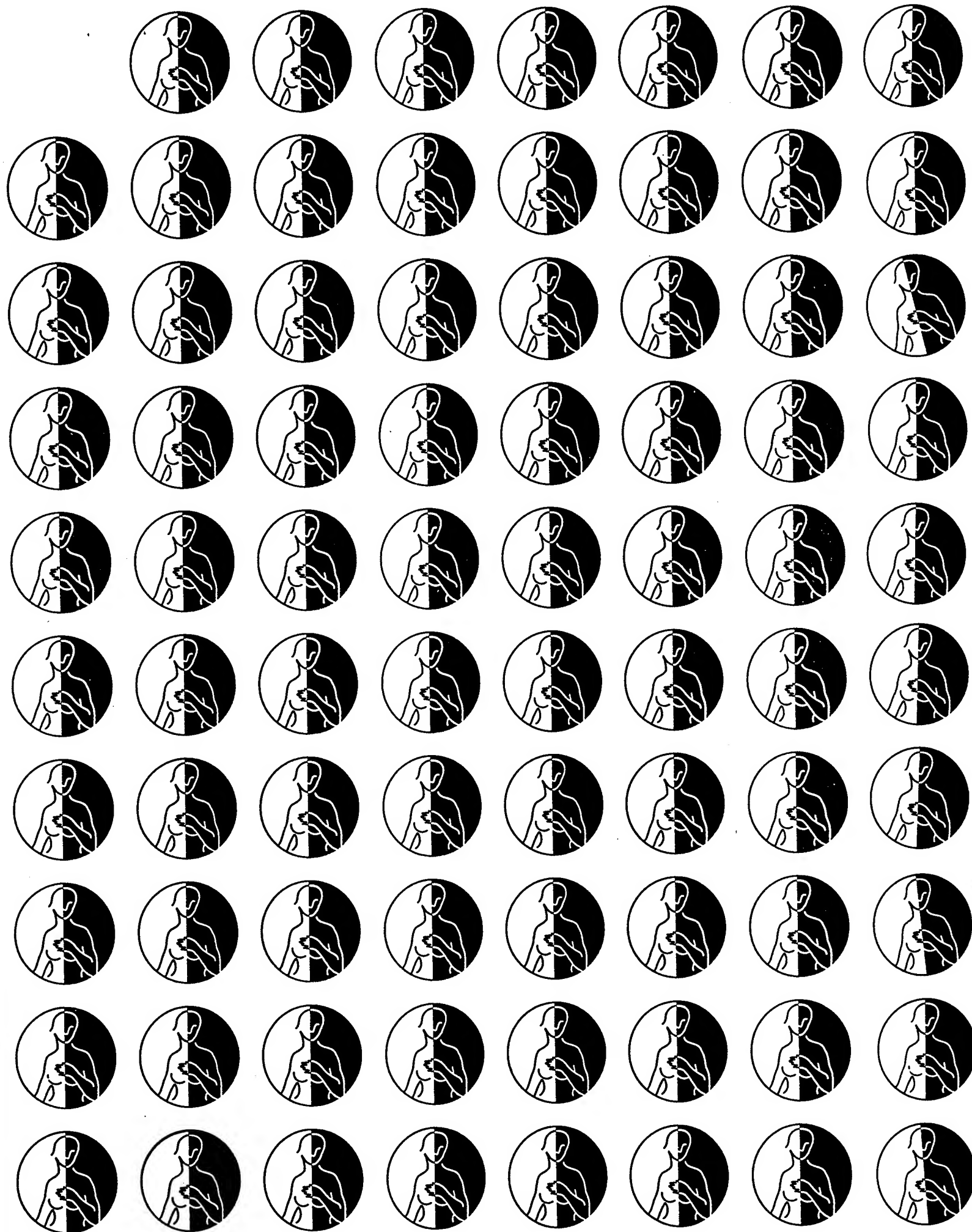


MANAGEMENT OF SKIN AND NIPPLE CHANGES ON OBSERVATION



MANAGEMENT OF OCCULT MAMMOGRAPHIC ABNORMALITY*





APPENDIX 5

Nurse Abstractor Training Manual

Nurse Abstractors Training Manual

Table of Contents

- I. Overview of the project
 - II. Responsibilities of the position
 - III. Employment information
 - IV. Key contacts
 - V. Abstracting Instructions
 - VI. Technical Support
 - VII. Paper Audit
 - VIII. Practice cases
 - IX. Quality Assurance
-

Overview of the Project

"Improved Follow-up of Breast Abnormalities Through Comprehensive Breast Care in Women 40 to 70 Years of Age"

Purpose of the Study

Breast cancer is an important preventable cause of illness and death among women. Unfortunately, physicians may misinterpret findings from women's history, physical and mammogram, resulting in delayed diagnosis or prolonged waits for reassurance. The focus of this study is to improve the knowledge, physical examination skills, and management skills of physicians.

The intervention will include three components:

- 1) Educational Session designed to enhance physicians' skills in appropriate follow-up and risk assessment of breast abnormalities and to improve the physicians' knowledge of the epidemiology of breast cancer and benefits of screening;
- 2) Clinical Skills Course teaching the optimal technique of clinical breast exam and interpretation of findings; and
- 3) Chart Reminder/Guideline System designed to improve recording, tracking and follow-up of women.

We hope to demonstrate that, for women 40 to 70 years of age, physicians receiving the special training will demonstrate a significantly greater increase in the rate of screening and improvement in the appropriateness and timeliness of follow-up of abnormal findings.

What residency programs are involved in the study?

The residency program sites include:

- 1) MidMichigan Regional Medical Center (Midland)
- 2) Saginaw Cooperative Hospitals
- 3) McLaren Regional Medical Center (Flint)
- 4) Genesys Health Systems (Flint)
- 5) Sparrow/MSU (Lansing)
- 6) Kalamazoo Center for Medical Studies
- 7) Munson Medical Center (Traverse City)
- 8) Providence Hospital (Southfield).

Four sites will be randomly selected to be intervention sites and the remaining four will be control.

What will be happening at each site?

At both intervention and control sites - Nurse abstractors will be performing chart audits on the charts of female active patients age 40-70 years of age. These nurses will be regularly sending information to MSU via the use of a laptop computer, which will be kept at the site for the duration of the project. Nurses will be abstracting charts during August through October 1999 and same months in 2000.

Intervention sites – Health care providers will receive the one day training in the summer of 1999 and are encouraged to use the chart reminder and follow-up form during the year after training. This chart reminder and follow-up form will be included in charts.

Control sites – Health care providers will receive a one day training (if they choose) in the summer of 2000 and have the option to use the chart reminder and follow-up system at that time.

This project is funded by the Department of Defense.

Responsibilities of the Position

This section describes the responsibilities and expectations for the Nurse Abstractor position.

GENERAL RESPONSIBILITIES

Training

1. Complete required two day training session to be held in East Lansing, Michigan in September/October.
2. Read and utilize the procedures outlined in the Nurse Abstractor Training Manual.
3. Actively work with Project Manager, Data Manager, and Nurse Trainer to clarify procedures as needed.
4. Acknowledge the importance of ongoing training, in the form of regular quality assurance meetings with Project Manager and Nurse Trainer.

Public Relations

1. Be flexible and courteous to other personnel in the Family Practice Center. You represent the MSU Essentials of Breast Health for Primary Care Physicians Project. You are a guest in the practice location. The continued support and assistance of the Family Practice Center staff is crucial for the success of this project.
2. Keep an identification letter from the study with you, in case of request and wear identification at all times (will be provided).
3. Clean up after yourself. Do not hold on to charts.

Quality Assurance

1. Conduct system quality assurance reviews of your own work, being thorough and reading through all records provided. Remember that errors can often be avoided by considerable attention to detail, careful thought, regular review, and asking questions when uncertain.
2. Participate in quality assurance reviews of audits done by others. Make corrections in a timely fashion as requested.
3. Participate in regular quality assurance meetings with Project Manager and or Nurse Trainer, noting problems and revising or modifying approach as needed.

Confidentiality

1. Maintain confidentiality for all audited information. Refer to patients by their ID numbers, rather than by name, whenever possible. If there is a need to discuss a particular case outside of the project areas, the Project Manager or Nurse Trainer should be contacted. Remember that the right of patient confidentiality should always be protected.
2. To insure confidentiality in your absence be certain no files or audit notes are left out or scattered about. All audits should be kept covered, in closed folders, or envelopes. All identifiers must be kept confidential whenever possible.

Security

1. You will be provided with a laptop computer for use with data entry. It will be your responsibility (with assistance from the site contact) to identify a secure place the laptop can be stored after working hours and when not in use. The laptop will need to be stored in this place when not in use.
2. As well, it is important that use of the laptop be secured with a password. Using a password will prevent others from accessing the data. It is your responsibility to assign (with assistance from the data manager) a password and utilize it for entry into the data screens.
3. Project goals and hypotheses. It is important that we not jeopardize the study by letting others know specifically what data we are abstracting. Although important at intervention sites, this is especially true at control sites. It is your responsibility to not divulge the specific aims of the project. If others inquire, refer them to the Project Manager or Principal Investigator.

Employment

1. Complete hiring packet information.
2. Complete weekly timesheets and turn in to the Project Manager by the date specified.
3. Notify the Project Manager in advance if total hours per week will not be met (i.e. sickness or vacation prohibits 19 hours/week).

SPECIFIC RESPONSIBILITIES

Identification and "Pulling" of Patient Medical Records (Charts)

At some locations, it may be necessary to pull charts of patients for the study. This will include the following tasks:

1. Locating patient medical records area
2. Identifying process for pulling medical records
3. Learning method of records organization and how to identify selected patient's records.
4. Identifying locations where medical records may be abstracted
5. Identifying proper procedure for use and returning medical records.

*These tasks will be explained by your site coordinator at your orientation meeting.

Eligibility Determination

It is important that you audit charts for patients that are eligible for the study. Auditing charts of patients that are not eligible will cause errors in our data. The following tasks are included in this process:

1. Gathering report of all potential eligible patients (criteria: female, 40-70, active patient). This will be provided to you by the site as you begin.
2. Determining eligibility for various aspects of the study (ineligible, eligible for guideline insertion and eligible for guidelines and abstracting). There is a specific form that you will be completing (on the laptop) which will help you to determine eligibility.

Audits

1. Complete audits each week, as assigned and FTP by Friday to data manager.
2. Complete and return reports to Project Coordinator as needed.
3. Notify Project Coordinator of any problems that occur, for example, with chart availability, documentation, personnel, or audit assignments.
4. If uncertain of anything, ask Project Coordinator for clarification.
5. Accuracy in abstracting data will be checked twice by a quality assurance auditor. It is important that you achieve and maintain a 90% or higher accuracy rate.

Communication

1. You are required to provide a weekly report to Barbara Given by email (bgiven@msu.edu). This due Friday by 5 PM each week. In this report, you are to outline:
 - a) what you have accomplished, as far as number of charts abstracted
 - b) problems with staff or getting charts
 - c) difficulty with criteria
 - d) general questions
 - e) plan for work for the following week
2. Failure to provide reports three weeks or more will result in termination. Only one warning will be given.
3. All questions that relate to auditing (this does not include technical questions or employment related questions) are to be directed first and only to Barbara Given unless she directs you otherwise.

Employment Through MSU

Employee Status

In this position, you are hired as a temporary, on-call employee.

Period of Employment

You will be employed for the following periods of time:

- MSU training to be held October 16-17 (includes travel time)
- Time at family practice site abstracting
 - Begins November 1st (or that week) and ends at the completion of work (estimate of 3-5 months)
 - 19 hours per week

Getting Paid

As an MSU Employee, you will need to regularly complete Time sheets in order to get your check. Included in this section are:

- MASTER copy of a timesheet. Use this to make copies to complete and send in.
- LISTING OF SUBMISSION AND PAY DATES. This lets you know when we need to receive your timesheet and when you should receive your paycheck, if submitted on time.

Probably the best way to get time sheets in is by fax. If you wish to get paid on time, fax by **10 AM on the Friday** ending a pay period. Please fax to:

Jodi Holtrop, PhD, CHES
(517) 355-7700

Address (FYI) is:

Jodi Holtrop, PhD, CHES
Department of Family Practice - MSU
B101 Clinical Center
East Lansing, MI 48824

Jodi will sign your time sheet and forward on to the appropriate individual at the University.

If you do not receive a check, please contact Maria Struck. She will check into the status of your pay check.

Please remember that it is important that you send in your time sheets and they are received by or before the dates listed on the enclosed listing of submission dates!

Michigan State University
DEPARTMENT OF FAMILY PRACTICE
B100 Clinical Center
East Lansing, MI 48824
(517) 353-3544, ext. 432
Fax: (517) 355-7700

DOD GRANT TIME RECORD

Name _____
 Social Security No _____
 Two-week period from Monday, _____

DATE	TRAVEL TIME (if any*)	HOURS WORKED	TOTAL
Mon			
Tue			
Wed			
Thur			
Fri			
Sat			
Sun			
TOTAL WK 1			
Mon			
Tue			
Wed			
Thur			
Frid			
Sat			
Sun			
TOTAL W 2			
COMBINED TOTALS			

(*Travel must be pre-approved by grant coordinator and applies to off site seminar or training sessions only; NOT travel to work site.)

 Nurse Signature

 Date

 Supervisor Signature

 Date

Please fax completed time sheet to Jodi Holtrop by 11:00 am Fridays.

MRS/11/06/00

Key Contacts

Dorothy Pathak, Ph.D., M.S. – Principal Investigator and Professor, Family Practice and Epidemiology

(517) 353-0772 ext. 441; pathak@pilot.msu.edu

Dept. Family Practice - MSU, B100 Clinical Center, E. Lansing, MI 48824

Jodi Holtrop, Ph.D., CHES – Project Manager and Assistant Professor

(517) 353-3544 ext. 432; jodi.holtrop@ht.msu.edu

Dept. Family Practice - MSU, B100 Clinical Center, E. Lansing, MI 48824

Barbara Given, Ph.D., R.N. – Co-Investigator, Professor of Nursing, and Research Director, Institute for Managed Care

(517) 432-4326; bgiven@pilot.msu.edu

Institute for Managed Care – MSU, D133 West Fee Hall, East Lansing, MI 48824

Suiying Huang - Data Coordinator

(517) 353-8623 ext. 149; huangsu1@msu.edu

Dept. of Epidemiology

Maria Struck – Support for grant

(517) 432-2794 ext. 458; maria.struck@ht.msu.edu

Dept. Family Practice - MSU, B100 Clinical Center, E. Lansing, MI 48824

Janet Osuch, M.D., M.S. – Co-Investigator, Professor of Surgery

(517) 353-3140; osuch@pilot.msu.edu

Dept. of Surgery, B424 Clinical Center, E. Lansing, MI 48824

Henry Barry, M.D., M.S. – Co-Investigator, Associate Professor of Family Practice

(517) 353-0851 ext. 456; henry.barry@ht.msu.edu

Dept. Family Practice - MSU, B100 Clinical Center, E. Lansing, MI 48824

G. Marie Swanson, Ph.D., M.P.H. – Co-Investigator, Professor of Family Practice and Director of the Cancer Center at MSU

(517) 353-3843 ext. 452; swansong@pilot.msu.edu

Dept. Family Practice – MSU, B108 Clinical Center, E. Lansing, MI 48824

Site Contacts

Site contacts are those individuals who will assist you at the Family Practice Residency Program. A list of names and phone numbers is below. Please arrange with you nurse partner for a meeting with this person for a site orientation. Thank you.

Site	Person	Phone Number
St. Lawrence	Linda Sirmeyer, Clinic Manager	517-377-0593 Fax: 377-0327
Sparrow	Chris Beaver, Clinical Manager	517-364-5767 Fax: 364-5718
Midland	Jim Baker, Office Manager	517-839-3344
Kalamazoo	Carol Tolis-Bucklin, Nurse Manager	616-337-6413
Saginaw	Teri Spear, Charge Nurse	517-583-6810
Traverse City	Vicky Rousseau, FP Center Manager	616-935-8034
McLaren	Nancy Konopnick, Office Manager	810-733-9658
Genesys	Ann Jagelo, Quality Assurance Auditor	810-762-8914
Providence	Frank Sutter Practice Manager	248-424-5373

at (517) 432-4326 or Jodi Holtrop, PhD, at (517) 353-3544 ext. 432.

Pilot account used for Michnet connection:

	Username	Password
Site 1: Sparrow	<u>Mcafee11@pilot.msu.edu</u>	password
Site 2: St.Lawrence	<u>Dobias11@pilot.msu.edu</u>	password
Site 3: Kalamazoo	<u>Petergeo@pilot.msu.edu</u>	password
Site 4: Midland	<u>Horvath3@pilot.msu.edu</u>	password
Site 5: Saginaw	Susan Davis' own pilot email account	
Site 6: Genesys	<u>Debermic@pilot.msu.edu</u>	password
Site 7: McLaren	<u>Taylo255@pilot.msu.edu</u>	password
Site 8: Traverse City	<u>Wilmotma@pilot.msu.edu</u>	password
Site 9: Providence	<u>Dwormanc@pilot.msu.edu</u>	password

Emails addresses for abstractors:

Email address	Username
Site 1: Sparrow TBD	
Site 2: St.Lawrence <u>Aileen.Quitos@ht.msu.edu</u> TBD	quitosai
Site 3: Kalamazoo TBD	
Site 4: Midland <u>Stephanie.Leibfritz@ht.msu.edu</u> <u>Elizabeth.Horvath@ht.msu.edu</u>	leibfrst horvatel
Site 5: Saginaw <u>Susan.Davis@ht.msu.edu</u>	davissu
Site 6: Genesys TBD	
Site 7: McLaren <u>Marion.Taylor@ht.msu.edu</u>	taylorma
Site 8: Traverse City TBD	
Site 9: Providence <u>Cheryl.Dworman@ht.msu.edu</u> TBD	dwormach

Instruction for Data Entry (DOD project)

This section will provide instruction on entering data onto data entry forms provided on your laptop computer.

To Do's in Chart Familiarity:

It is first important to familiarize yourself with how the medical record (chart) is organized. Each Residency Program will have it's own system. It is important to be familiar with the medical record so that you may quickly find the information you are looking for, as well as not miss anything important. Here are some things to think about when doing so:

- General chart organization.
 - In what sections do you find a record of office visits?
 - Where are examination results (are they typed or hand-written)?
 - Determine what forms are used for phone calls so that you can distinguish phone calls from visits.
 - Mammogram reports?
 - Ultrasound reports? (Make sure you are clear whether you are reviewing mammogram reports or ultrasound reports, as they can look very similar).
 - Pathology reports
 - Surgeon's letters
- Determine if the chart begins with the most recent visits (i.e. they are on top) or the most recent visits are toward the back of the chart.
- Get list of who is a resident, faculty member and PA or Nurse practitioner so when you see a name you will know what category they go in and the individual code that's assigned. You will be entering codes assigned to the individual resident, faculty, physician assistant and nurse practitioner. If there are two signatures, that is resident/PA/NP and faculty physician, the code for resident/PA/NP should go into Provider 1 field. Faculty physician into Provider 2 field. Ask if there are any people who were residents and are now faculty. There are some cases where this occurs, so you'll need to find out what year they were in which position.
- Become familiar with common abbreviations and symbols such as PH meaning Personal History.

- ACS guidelines are a 12 month mammogram and 12 month CBE for ages 40 and over. If you see this noted in follow-up plan as "Follow ACS Guidelines" this, you'll know that's what it means. However, we also provided you with an option of "ACS guidelines". So, all you need to do is to chose that option.

Getting Into the Program:

To open the program, follow these steps:

1. Turn on the computer
2. Double click on the icon that says 'NewBreastCare'
3. The database designed for this study contains **four** forms for you to work on.
4. The first form '**Form I-Front-End**' will automatically open. It contains patient's general information, eligibility criteria, and part of chart review form (Questions 1-5).
5. The second form '**Form II-Visit Entry**' is connected to the Form I through linking buttons. The purpose of the visit, presenting symptoms, and CBE documentation need to be recorded in this form.
6. The third from '**Form III-Test Result Entry**' is connected to the Form II and Form IV through linking buttons. All types of tests results, such as mammogram, FNA, FNAB, ultrasound, Biopsy, are recorded in this form
7. The forth form '**Form IV-Follow-up Entry**' is connected to the previous Forms through linking buttons. This form collects all the assessment and recommended follow-ups.

The information you see on the screen corresponds with the first data form in the computer. Before you proceed with entering data, there are few key things to keep in mind:

As you begin using the program, keep in mind these points to help you enter information and find your way around.

Scrolling—You may use the arrows in the vertical bar on the right-hand of the screen to move up and down to the beginning or end of the form.

Navigating—

FOR MOVING BETWEEN FORMS OR NAVIGATING WITHIN FORM I AND II, USE ONLY THE NAVIGATING BUTTONS PROVIDED ON TOP OR BOTTOM OF EACH FORM. DO NOT USE THE ARROW BUTTONS ON THE BOTTOM OF THE DATABASE. THIS DOES NOT CARRY THE STUDY ID TO THE NEW FORM.

When you are in Form I, **the horizontal bar at the bottom** of the screen gives you the information as to how many individuals are in your database. You can move between patients but be careful. Similarly when you are in Form II, the horizontal bar tells you how many encounters you have for that person. Again you can move between encounters if you are careful, **but make sure you do not use that method to add a new visit. Navigating with the horizontal bar buttons does not carry Study ID to the next encounter form.**

Closing Form or Database—At the top of the screen, you see two sets of 3 small buttons with the following symbols:

- 1) an underline for minimizing the screen;
- 2) a two overlaid little squares for restoring the screen to smaller size; one little square for maximizing the screening; either one will appear.
- 3) a "X" symbol for closing the screen.

The upper set corresponds to the screen of the current ACCESS database; the lower set to the screen of the current object, such as forms, tables, etc.

To close the ACCESS application, click "X" in the upper set; To close the form you are currently working on, click "X" in the lower set.

Entering Information – Can be performed by using either the [Enter] or [Tab] keys, or moving the mouse to the appropriate field and click.

There are three types of data entry.

- 1) When you see a rectangular box, you will need to type in the required information;
- 2) When you see a rectangular box with an arrow at the end of it, click on the arrow, it will give you pull-down options for this field. Select the appropriate option.
- 3) When you see a little square, you will need to click on this square and a check mark will appear indicating 'Yes'.

Correcting Information – If you make an error,

- 1) in the rectangular box, put your cursor at the beginning and hold the left mouse button and drag the cursor to select all the information. This will make the selected area shaded. Then release your left mouse button and hit the delete button on your keyboard. Then type the new information.
- 2) in the rectangular box with arrow, click the arrow and select the appropriate option. It will overwrite the previous choice.
- 3) in the little square, click once to de-select your previous choice (the check mark will disappear).

Required Data Entry Fields

- **On the Form I**, there are two required fields—New Study ID and Today's Date

- 1) If you do not fill out new study ID, or have a duplicate ID number, or you did not enter today's date, a warning message box will appear when you click the button in the first form, titled 'Click here to continue', or click the button titled 'Continue to record visit info.'. You should click 'OK' on the message box, it will always take you back to the new Study ID box. If the new study ID field is empty, fill in appropriate new study ID; if there is a new study ID, but the field 'Today's date is empty, fill in today's date; if both new study ID and Today's date are filled, that implies this new study ID is duplicate. Please check and correct.

New study ID will remain the same for all patients whose eligibility status did not change from last year (8/1/98 - 7/31/99) to current (8/1/99 - 7/31/00). In these situations, simply leave old Study ID unchanged. For patient whose eligibility status changes for the current year, fill in the appropriate Study ID in the new Study ID field by consulting the last ID number assigned.

- 2) If you try to exit the form by clicking "X" symbol in the lower set but these required fields are not appropriately entered, you will see two messages. The first will give you a warning indicating information is missing; when you click 'OK' on this message box, the second message box appears. If you click 'Yes', you will exit this form without saving that record. If you click 'No', you will have a chance to enter/correct the missing/duplicate information.

- **On the Form II-Visit Entry form**, there is one required field--Question 6. Date Breast Care Activity was recorded.
 - 1) If you do not fill out the date of visit in this field, a warning message box will appear when you click the button titled 'Add new visit' or 'Add new patient'. You should click 'OK' on the message box; it will always take you back to the Question 6 box.
 - 2) If you try to exit the form by clicking "X" symbol in the lower set, but this required field is missing, you will see two messages. The first will give you a warning indicating information is missing; when you click 'OK' on this message box, the second message box appears. If you click 'Yes', you will exit this form without saving that record. If you click 'No', you will have a chance to enter the missing information.

Saving Information – You do not need to select 'save' anywhere to save data. After you enter the information for each field it automatically saves it. When you exit, it saves the data. The only exception is that when the information in the required fields is missing and you exit that form.

Searching Information – When you see the binoculars, this means you may search. You must first click on the field that you wish to search and then move the to binoculars and click on it.

You will use Search more often this year than last year, because you will add visits to old data that were abstracted last year.

The preference of Search is:

- o Medical Record Number
- o Last Name
- o Date of Birth (you must search as 00/00/00)
- o Study ID that were assigned last year

Blue shaded boxes – These boxes are automatically filled out based on the information you provided previously. You have no access to change this information.

Disabled fields—appear faded on the screen. When a leading category has been checked, these fields will be enabled and represent options that will need to be selected.

Skip Pattern—Certain fields when selected will trigger a message box indicating a skip pattern. Click 'OK' on that message box and you will be automatically taken to that question.

Note:

- Currently when you choose in Type of Contact (Question 6) any one of the test results, you will be taken directly to Form III-Test Result Form by clicking the button on the right.
- Similarly, if you choose Surgeon's letter, you will be taken directly to Form IV-Follow-up Form at "Assessment/Recommended Follow-up From Surgeon's Letter".

FPC— This stands for 'Family Practice Center.' This means the care was provided by a provider from the Family Practice Center rather than another institution.

FPCP—This stands for Family Practice Center Provider.

The following steps describe how to add new patient and visit.

Start entering information beginning with the first screen.

Last name – Insert patient last name

First name – Insert patient first name

Medical record number – Enter. This field will accept either number or letters. If no information is available, leave it blank.

Date of birth – All date type of fields are entered as 3 sets of numbers starting with month, day, and year, such as 08/10/99 indicating August 10, 1999. Slashes automatically pop-up when you go to enter. When you start entering the date, make sure your cursor at first place-hold, i.e. at the first digit for the month entry. To avoid errors, enter all leading 0's, such as '08'. You will notice after you entered date and move to the next field, the leading '0' for month and day will not show on the screen.

Abstractor ID – You will be given an 2-digit ID number. Enter that number here.
Please fill in your 2-digit abstractor ID here: |____|____|

For your information, the following table lists the site number and abstractor ID.

Site			Abstractor ID	
1	Intervention	Sparrow (includes Mason)	11=Tara Johnson	12=J.Anderson
2	Intervention	St. Lawrence	21=A. Quito	22=V.Johnson
3	Intervention	Kalamazoo	31=B.Pruim	
4	Intervention	Midland	41=S.J. Leibfritz	42=E. Horvath
5	Intervention	Saginaw	51=S.K. Davis	
6	Control	Genesys	61=K.Atwell	62=B.Buckles
7	Control	McLaren	71=M. Taylor	
8	Control	Traverse city	81=K.Remus	82=L.Geiser
9	Control	Providence	91=C. Dworman	92=L.Biskup

Eligibility Criteria Section:

- Complete each of the questions # 1 through 5. Click the arrow on the right of the field for a pull-down of choices. Point your mouse arrow and click on the choice you wish to select.

To provide options for new patients entering the practice during this year, as well as patients leaving the practice for various reasons, we added two questions:

Question 2a asks: Date of the very first visit to the FPC provider.

Question 5a asks: Is there documentation patient left practice before

7/31/00?

This field has the following options:

N/A, Death, Transferred, Move out of town and other specify.

If patient left practice, provide date.

2. After completing all 5 questions, click the button 'determine eligibility code.' To the right, in a blue shaded field, a code will appear of 1, 2 or 3. For your information, the computer comes up with the eligibility code based on your answers to questions 1 through 5:

- Eligibility code=1 when the answers are: FEMALE to criteria 1; YES to 2 and 3; FPC Provider to 4; and YES to 5
- Eligibility code=2 when the answers are: FEMALE to criteria 1; YES to 2 and 3; FPC Provider to 4; and NO to 5
- Eligibility code=3 for all others

3. On Question 5, if no breast care visit, but mammogram or mammogram reminder in chart, do the followings:

- Enter "FPC Provider" to Question 4, and "Yes" to Question 5
- This will count this patient as an active patient with an Ecode = 1
- Enter 0 as the Total Number of Visit (Question #3)
- For question #4, Was A Breast Care Performed During Any of The Visits Within The 15 Months Period, you should answer YES, and go on to the visit entry to record the information
- Answer "Other" on Type of Contact (Question #6)
- Answer "Other" on Purpose of this Visit/Call (Question #7)
- Then specify in the comment box

Eligibility codes and actions

Eligibility code = 1: Eligible for abstracting

Eligibility code = 2 and 3: Not eligible; No further action is needed

Assign a study ID—Study ID is a 6-digit number. Using this guide to assign a study ID as follows:

Digit	1 st	2 nd	3 rd	4 th	5 th	6 th
Study ID=	Site Number	Eligibility Code	Assigning consecutive number			

Site numbers and eligibility code see above.

If you are at a control site (site 6, 7, 8, 9), there are only two categories really: These are 1 = eligible for abstracting and 2 & 3 = not eligible. Because we are not inserting guidelines in the chart, category 2 is not applicable.

Thus, those in category 2 become category 3's. Keep the study ID as 2 for the second digit, however, know that they are essentially ineligible.

The 6-digit study ID is a unique identifier for each patient. Patients at your site have the same 1st digit. If they have the same status of eligibility, they will also have the same 2nd digit. But the last four consecutive numbers should be incremented. Look at the last 4 numbers entered for the category (1, 2 or 3) of eligibility code you are in. Under study ID, there two boxes: one explains how to assign a study ID number, the other (blue shaded) shows the last study ID number assigned in each category of eligibility. After you enter first two digits of study ID number, You should find out what was the last 4 digit number assigned for that specific eligibility category. Use the next consecutive number.

Same study ID number cannot be assigned twice – it will not be accepted.

New study ID will remain the same for all patients whose eligibility status did not change from last year (8/1/98 - 7/31/99) to current (8/1/99 - 7/31/00). In these situations, simply leave old Study ID unchanged. For patient whose eligibility status changes for the current year, fill in the appropriate Study ID in the new Study ID field by consulting the last ID number assigned.

Today's date – Same instructions as date of birth. It is a required field.

At this point, you are given two choices:

- 1) If this patient is eligibility code 2 or 3, after you assigned study ID and entered today's date, you can click button 'Search / Add New Patient' and start with a blank screen to do your next patient.
- 2) If this patient is eligibility code 1, after you assigned study ID, entered today's date and stamped the documents, then you click button 'Click here to continue' (This button will check if you assigned appropriate study ID and filled in today's date) and then you simply continue abstracting and adding to this form.

Identifying Follow-up Guidelines And Summary Breast Care Sheet With The DOD Project

At all intervention sites, we need to check if the guidelines and Summary Breast Care Sheet (the white sheet) were inserted for all eligible patients. We are also interested in knowing if the physicians used the Summary Sheet to document additional breast care.

You will also need to stamp the guidelines and Summary Sheet so that these documents are identified as a part of a research project.

To implement this, we added two questions on the first form (Form I – Front-End Form).

The first question checks if these documents were inserted and if additional information can be found on the Summary Sheet. The choices are:

"Guideline Inserted"; "Guideline Not Found";

"Summary Sheet Inserted"; "Summary Sheet Not Found";

"Additional Information on Summary Sheet";

"No Additional Information on Summary Sheet";

The second question remind you to stamp these two documents. The choices are:

"Guideline Stamped"; "Summary Sheet Stamped";

"Both Stamped"; "N/A Guidelines"; "N/A Summary Sheets";

FORM I:

1. Date of most recent visit – Enter in. Again, remember to put in two digits for each month, day and year.

We have put in logical check that will not allow you to enter for the Date of Most Recent Office Visit dates after 7/31/00. This is used to autocalculate the last eligible visit within the last 15 month.

However, in order for us to track the three months follow-up for any breast problems/results of tests, you will be asked to additionally abstract all breast care visits for the time period of 8/1/00 to 10/31/00. Thus, in reality, you will be abstracting the usual 15 months + 3 additional months of data. The dates on Form II are not restricted to end at 7/31/00.

2. Date of last eligible visit for audit—This date is automatically calculated for you. It tells you how far back to go and audit this chart (15 months). Review all records including office visits, breast care phone consultation, mammogram, and other test results in this chart from that date forward.
3. Enter the total number of visits—
- Count all family practice office visits (These are all types of visits, not just breast care).
 - In addition, count all phone calls for breast care.
 - Do not count phone calls for other concerns.
 - Do not count visits to oncologists, radiologists, etc, even if that information is available in the chart.
 - Do not count phone calls to family practice physicians regarding refills of Tamoxifen/Nolvadex, if it is for treatment of breast cancer. However, if it is specified that tamoxifen is prescribed for prevention, then it will be counted as an encounter. You would then record that information in the general comment box provided in the follow-up form (Form IV)
4. Was breast care performed?--During the time period, was there any breast care performed? Select yes or no. If the answer is NO, the patient is not eligible for further abstracting. You are done with this patient. If you wish to continue to next patient, click button 'Add New Patient'. Otherwise, you click 'X' to exit.
5. Personal/Family History of Breast Cancer--Select choice from:
- None - Select if there is documentation that the patient has no personal / family history
 - Yes – Select if noted personal/family history
- For age at diagnosis, You should:**
- Fill in exact age when information is available;
 - Fill in '777' if only known Pre-menopausal, less than or equal to 50 years old;
 - Fill in '888' if only known Post-menopausal or greater than 50 years old;
 - Enter 999 for don't know;

If in self:

- If available, document type of surgery
- If available, specify all treatments
- Undocumented – Select if not mentioned if there is family history or not.
- Patient Don't Know – Select if documented that patient doesn't know family history.

Note: There might be times as you review the chart, that the family members' age at diagnosis will be mentioned in, say, mammogram report, Please go back than to Form I and record that information.

At the bottom of the Form I, four navigating buttons can be used to move from patient to patient within the first form:

- **Go to first patient**
- **Go to previous patient**
- **Go to next patient**
- **Go to last patient**

To continue record information for individual visits, click the button 'Continue to record visit info.', it takes you to the Form II

FORM II:

After you click the button 'Continue to record visit info.' on Form I, Form II will appear for you to enter patient's visit or related phone consultation information. On this form you also enter in the "type of contact" whether it is a test result or surgeon's letter. For these two options you will be prompted that you can go directly to the "Test results form" or "Surgeon's letter form". To whatever form you go the **study ID number and date of last eligible visit in the first form will be automatically carried over to this form.**

6. Date any breast care performed – Enter in the date following the same rules as for date of birth;

For VISITS or PHONE CONSULTATIONS enter the date it occurred.

For TEST RESULTS or SURGEON'S LETTER use the date it was received in the FP files (if stamped) as the date of the encounter. If that is not available but the date FPCP reviewed the results is available use that date. If neither date is available use the date the test was done as the date for the encounter.

Type of contact: Select choice from a pull down list.

- **If you choose office visit or phone call consultation**, you should go on and fill out the rest of Form II.
- **If you choose any of the test results listed**, a message box will appear to inform you that you will be taken to Form III-Test Result Form by clicking the button on the right. You will skip the rest of Form II.
- **If you choose 'Surgeon's letter' from the pull down list**, a message box will appear to inform you that you will be taken to Form IV directly.

7. Purpose of visit/call--Select choice from pull-down.

If you selected choice 2, 3, 4, 5, or 8, you have to specify in the box underneath.

8. Who performed breast care-- On several charts, you will see the name of a resident and a faculty physician. If there is a resident name, select resident even if there is a faculty name. Faculty must sign off on resident records for billing purposes. If the faculty physician is seeing the patient without a resident, then select Faculty physician. You will be entering

codes assigned to the individual resident, faculty, physician assistant and nurse practitioner. If there are two signatures, that is resident/PA/NP and faculty physician, the code for resident/PA/NP should go into Provider 1 field. Faculty physician into Provider 2 field.

9. Presenting symptoms--Check all that apply.

- If purpose of this visit is "Presenting Symptom", then specify which breast and check the appropriate abnormality category. The options under 'Skin/nipple change' will be enabled if 'Skin/nipple change' has been checked. Same is true for the option 'Occult Mammographic Abnormality'.

- If the purpose of this visit is "Screening/Well Women Exam/Annual Exam", or any other health problem, but a problem related to breast abnormality is mentioned by the patient, then it should also be recorded as a presenting symptom.
- However, if the purpose of this visit is "Screening/Well Women Exam/Annual Exam", and there is no mention of a problem in the history, but during the examination, the physician discovers an abnormality, then this will be recorded as "none" for presenting symptoms and the details about the abnormality will go under "CBE findings".

10. CBE Documentation--Check 'Documented' (you can find documentation in chart) or 'Not done/undocumented' (if you cannot).

11. CBE Findings--Remember that this question relates to CBE and not to mammograms. Question 11 asks about CBE findings only.

- Check 'Bilateral Implants' if there is mention in the chart
- Check 'Mastectomy, which breast' if there is mention in the chart, then specify which breast
- Check 'Previous abnormality resolved' if on the follow-up visit there is documentation indicating that the problem resolved.

CBE NORMAL

- **Note re: QUALITY OF WRITTEN CBE DESCRIPTION.** The quality of written documentation for CBE appears separately under NORMAL findings and separately under ABNORMAL findings.

You will check 'Inspection', 'Palpation' or 'Lymph Node Examination' if at least one of the criteria, following these components of CBE has been mentioned in the chart. Notice that the default at the moment for each of the criteria is 'undocumented'. Please check each of the findings mentioned in the chart.

CBE ABNORMAL-- If there was an abnormality found, answer the question under Q11 regarding which breast(s) has abnormal finding? (a pull-down screen), then proceed to complete the pertinent information under the breast(s) with the noted abnormality.

Note – If you cannot determine which breast – follow the instructions noted on the screen and enter information under the left breast category. If both breasts have abnormalities, you need to record the information for each side.

There are four types of abnormalities that can be entered directly

- 1) Lump(s)/Mass(es)/Asymmetric breast thickening/Asymmetric Fibrocystic
- 2) Nipple discharge with no lump
- 3) Observational findings with no lump
- 4) Pain

Underneath each one additional detail about findings should be specified if available in the chart.

Location– Write in exactly as it is in the chart. Sometimes it will be written as clock position. Otherwise, simply type in the written descriptor of the location of the abnormality.

Specifically for each type of abnormality

Lump(s)/Mass(es)/Asymmetric breast thickening/Asymmetric Fibrocystic--You need to specify the lump size, depth, hardness, mobility, shape, and texture if available. If there are additional findings associated with Lump(s), such as observations on skin changes or nipple changes, these should be recorded in the appropriate boxes provided. Use the pull-down menu to select 'Yes' or 'No' based on the information on the chart. Note: The default entries for these fields are 'undocumented'.

Nipple discharge with no lump--Specify if Spontaneous, Color of discharge, Unilateral or bilateral, single vs multiple ducts.

Observational findings with no lump--Check all that apply

Pain--Check whether breast or chest wall or unspecified

Other--If the abnormality described does not fit into one of the four categories, check 'Other, specify' at the end of this box and write in the description from the chart.

Quality of written description of CBE documentation for Abnormal

Findings – The three components of CBE 'Inspection', 'Palpation', 'Lymph node examination', should be checked if at least one of the criteria that follows each component is mentioned in the chart. Additional information can be recorded in 'other, specify' box.

FORM III:

12. Mammogram Documentation – Click to pull down your answer choice. If on a particular visit, there is documentation in the chart that FPCP recommended or ordered mammogram, mark that the mammogram was ordered and the date. DO NOT include the results of the mammogram on this visit report, since they will be recorded separately under 'Mammogram results'. For 'Test results' enter the date stamped at the bottom of the report, that says when the results were obtained by the FPC. For 'results reviewed by FPCP' this is when the results were reviewed by the FPCP. It is okay to record any one or combination of the choices 1-4 if that is all that is available in the chart.

13a, 13b, 13c: Mammogram findings – Remember to fill in **which breast** was recorded on this specific mammogram result.

In Section 13a report the Category or description of the Final Impression, separately for each breast. Sometimes, especially for Category I, there will not be a separate mention of each breast, but only a mention of a Bilateral mammogram. Then the findings would apply to both breasts and you need to check Category I under each breast.

In Sections 13b we have provided you with options that are most often mentioned as mammogram findings so you do not have to write in the specific findings. If none of the categories provided can be checked, you still have the option of writing under 'Other'. Select all the categories that apply based on the result.

Section 13c needs to be filled out only when mammogram finding was dictated as Category II and up. Sometimes even for Category II you will not have location specified. It is O.K. under such circumstances not to record location.

13. Patient notified of mammogram findings--You can say 'yes' only if there is documentation on the test result that a card was sent, or patient was called, or some other comment that indicates that communication between patient and FPCP occurred. Provide date if mentioned.

15.Cyst-Fine Needle Aspiration (FNA)—Specify who performed this procedure by selecting the option provided in the pull down menu for the field 'Done by'. Also fill in the date done. If done by FPCP at the time of the visit when the lump was identified, enter for 'Date done' as the date of the visit. If this information is obtained from a Cytology report following fluid sent for analysis, either by FPCP or Surgeon, all the information should be entered as a separate contact under 'FNA results' and the provider should be specified if information available. Report results from Cytology report in the appropriate categories or write in 'Other'.

16. Patient notified of FNA findings and date?

You can say 'yes' only if there is documentation on the test result that a card was sent, or patient was called, or some other comment that indicates that communication between patient and FPCP occurred. Provide date if mentioned.

17.Solid Mass-Fine Needle Aspiration Biopsy. (FNAB).

Specify who performed this procedure by selecting the option provided in the pull down menu for the field 'Done by'. Also fill in the date done. If done by FPCP at the time of the visit when the lump was identified, enter for 'Date done' as the date of the visit. If this information is obtained from a Pathology report following specimen sent for analysis, either by FPCP or Surgeon, all the information should be entered as a separate contact under 'FNAB results' and the provider should be specified if information available. Report results of FNAB in the appropriate categories, or write in 'Other'.

18. Patient Notified of the FNAB findings from Path Report and date?

You can say 'yes' only if there is documentation on the test result that a card was sent, or patient was called, or some other comment that indicates that communication between patient and FPCP occurred. Provide date if mentioned.

19. Ultrasound findings.

If on a particular visit, there is documentation in the chart that FPCP recommended or ordered ultrasound, mark that it was ordered and the date. DO NOT include the results of the ultrasound on this visit report, since they will be recorded separately if there is an actual report in the chart.

20. Patient Notified of the Ultrasound Findings and date?

You can say 'yes' only if there is documentation on the test result that a card was sent, or patient was called, or some other comment that indicates that communication between patient and FPCP occurred. Provide date if mentioned

21. Image-Guided Biopsy/Open Biopsy Results

For Results received:--enter the date stamped at the bottom of the report that says when the results were obtained by the FPC. For 'results reviewed by FPCP' record the date when the results were reviewed by the FPCP if indicated. It is okay to record any one or combination of the choices 1-4 if that is all that is available in the chart.

Based on the results from the Pathology Report check all that apply for findings. If the provided categories do not include the description in the report write the findings in 'Other'.

FORM IV:

22. Recommended follow-ups(s)--If there is no documentation of any follow-up, check 'Undocumented'. Otherwise,

There are two sections here:

▪ **Follow-Up for Normal CBE and Mammogram (or one of them undocumented):**

Select the appropriate follow-up options provided in the box. If you checked 'Following Other Guidelines', you need to specify what was written in the chart and write in the space provided. You can always write other recommendations in the 'Comments' field.

▪ **Follow-Up for Abnormalities:**

Notice these are two sets of follow-up choices. On the left-hand side, you have follow-up options for specific abnormalities; on the right, you have follow-up options that can be recommended for any abnormality.

Please always check **ALL** the recommended follow-up options mentioned in this visit or test result.

Note the large box on the bottom right called 'Other recommendations or comments concerning Abnormality(ies).' Use this space to describe any additional recommendations / comments concerning this abnormality that does not fit into the categories described. Please make sure to make information in this section very clear as to what breast problem or abnormality is being addressed (such as pain, lump, etc.) and what was found. You can type in at most 250 characters in this box.

General Comments About this Visit

An additional box for comments was created at the end of Follow-up but before the Surgeon's letter follow-up. You should write overall comments regarding this visit in this box. For example if you have 'Other health visit' that mentions that CBE is due on a certain date, you would have an encounter where the only information recorded would be in that box. '

Surgeon's letter:

There is a big change in the way we will be recording information from Surgeon's letter. Much less detail.

- Rather than record everything that was described in the letter, we have created in the Follow-up Form, a section called Assessment/Follow-up From Surgeon's Letter. After you enter on Form II in "Type of Contact" Surgeon's Letter, you will be taken to this section directly, after you click O.K in the message box. You will have to check whether the referral diagnosis is confirmed or not. Whether additional tests were done/ordered by surgeon, and what is the recommended follow-up. This should shorten the time you have to enter data based on the Surgeon's letters

Situations: I—Add New Patient; II—Add New Visit.

What to do next after you entered information for one visit, or test result?

YOU ALWAYS HAVE TO GO THROUGH FORM IV-FOLLOW-UP FORM

FOR MOVING BETWEEN FORMS OR NAVIGATING WITHIN FORM I AND II, USE ONLY THE NAGIVATING BUTTONS PROVIDED ON TOP OR BOTTOM OF EACH FORM. DO NOT USE THE ARROW BUTTONS ON THE BOTTOM OF THE DATABASE. THIS DOES NOT CARRY THE STUDY ID TO THE NEW FORM.

In Form II and IV, you may:

- Click 'Add new visit' – Use this if there are other visits/test results for breast care within the auditing time frame. You will be given a blank screen to start over to fill in information from the next visit. *You will start again with Q 6.*

In Form IV, you may also:

- Click 'Search / Add new patient'—Use this if you go on to record new patient. After clicked this button, this form will be closed and you will be taken back to the Form I.

By now we have taken you through the steps involved in **Situations: I—Add New Patient; II—Add New Visit.**

Suppose you want to update, please follow the steps described below:

Situation III—Update information on Form I for an existing patient:

(You are on Form I.)

1. Move your mouse to the box titled 'Please assign study ID' and click inside of it. You should see your cursor inside the box.
2. Now move your mouse to the binocular button on the upper left-hand corner and click.
3. A dialog box titled 'Find in Field: 'Study ID'' will appear on the screen. In the line titled 'Find What', type in the study ID for the patient you are searching.
4. Click the button at the end of the line titled 'Find First'. The patient's record will appear on the screen.

5. You need to **overwrite today's date** (please follow the instructions for 'correcting information' to type in today's date),
6. You can now proceed with the update.

If you would like to search by patient's last name rather than by Study Id, in step 1, you would move your mouse to the box titled 'Patient Name (Last)' and click inside of that box. Then proceed with step 2. At step 3, the title of the dialog box is 'Find in field: Lname'. Type in the patient's last name in line titled 'Find What' and hit the button 'Find First'. The patient's record will appear.

We have given you two examples of how to search by a given field of interest. You can also search by patient's medical record number, or date of birth.

Situation IV—Update information on Form II, III, or IV for an existing patient:
(You are on Form I)

1. Move your mouse to the box titled 'Please assign NEW study ID' and click inside of it. You should see your cursor inside the box.
2. Now move your mouse to the binocular button on the upper left-hand corner and click.
3. A dialog box titled 'Find in Field: 'Study ID'' will appear on the screen. In the line titled 'Find What', type in the study ID for the patient you are searching.
4. Click the button at the end of the line titled 'Find First'. The patient's record will appear on the screen.
5. You need to overwrite today's date (please follow the instructions for 'correcting information' to type in today's date).
6. Click the button, on the bottom of the form, 'Continue to record visit info.', it takes you to the second form.
7. Move your mouse to the box of Question 6-Date of Breast Care Activity Was Recorded' and click inside of it. You should see your cursor inside the box.
8. Now move your mouse to the binocular button on the upper left-hand corner and click.
9. A dialog box titled 'Find in Field: 6. Date of Breast Care Activity...' will appear on the screen. In the line titled 'Find What', type in the date for the visit you are searching.
10. Click the button at the end of the line titled 'Find First'. The patient's visit will appear on the screen. You can now proceed with the update.

Possible Error Messages and Their Interpretation

1. *"The changes you requested to the table were not successful, because they would create duplicate values in the index, primary key or relationship. Change the data in the field or fields that contain duplicate data, remove the index, or redefine the index to permit duplicate entries and try again."*

This message means you have a duplicate study ID or the study ID field is left empty. It's a protective device to make sure you assigned a correct study ID. Please go back and check if study ID was properly assigned.

2. *"You can't save this record at this time. Microsoft Access may have encountered an error while trying to save a record. If you close this object now, the data changes you made will be lost. Do you want to close the database object anyway?"*

This message usually appear after message 1, after you click ok to make message1 disappear. If you choose YES (close the database object anyway), and not to make changes in the study ID field, this record is not saved. If you choose NO, you get a chance to go back and change study ID field, and make it either not empty, or not duplicated.

3. *"You can't go to the specified record: you may be at the end of a recordset"*

This message can be caused by two reasons: first, you maybe at the end or the frontmost of a recordset. You may have clicked "Go To Previous Record" while you are already on the first record. Second, this message could mean study ID field is left empty or duplicated, or if the field for today's date (which is right next to the field for studyid) is not filled in.

4. *"The field 'tblFront-End.Date' can't contain a null value because the required property for this field is set to true. Enter a value in this field"*

This message appeared because the field for today's date (which is next to the field for studyid) is not filled in. This is another protective device to make sure you entered today's date. If you want to save this message, click OK to this message, then click NO to the next message box, which will give you a chance to go back and correct the incorrectly filled fields. If you do not want to save this particular record, click ok to this message, then YES to the next message.

5. *"The field 'tblFront-End.StudyID' can't contain a null value because the required property for this field is set to true. Enter a value in this field"*

This message appeared because the field for study ID is not filled in. Study ID is required for each patient. If you want to save this message, click OK to this message, then click NO to the next message box, which will give you a chance to go back and correct the incorrectly filled fields. If you do not want to save this particular record, click ok to this message, then YES to the next message.

6. *"The field 'tblVisit1.date' can't contain a null value because the required property for this field is set to true. Enter a value in this field"*

This message appeared because the field for "Date of Visit", or Question 6 On the second form was not filled. This is a required field in order to save the particular record. If you want to save this message, click OK to this message, then click NO to the next message box, which will give you a chance to go back and correct the incorrectly filled fields. If you do not want to save this particular record, click ok to this message, then YES to the next message.

Special Cases/Questions:

Q: What do I do if pages are missing and data is not there?

A: Put in what you can determine from what is there.

Q: What do I do with transposed dates?

A: If you are sure that it is a transposition, then put it in as it should be. If you are not sure, put it in as it is stated.

Q: What do I do with lots of missing dates?

A: Put in what you can, leave blank missing dates.

Q: Do I count phone calls as visits?

A: Generally, no as part of the count of overall number of visits. However, count phone calls for the number of visits if they have to do with breast care. It is a good idea to familiarize yourself with the forms used at your site for phone calls so you may easily identify phone consultations versus regular visits.

Q: What do I do with prophylactic mastectomy?

A: Write this information in the 'General Comments about this visit' box that has been provided in the Follow-up Form. Do not forget to do this, since that box appears at the end.

Additional Information To Consider

1. Suppose you worked on the visit form and want to go back to the first or front-end form, you can do this by clicking the button "Go Back to Front-end" on the top of the visit form.

However, when you do this, we have secured the visit you are working on is connected to the specific patient. Therefore, you will notice on the bottom bar of the screen, 1 of 1 (Filtered) on the first or front-end form. To go back to your full data set, you need to click on the highlighted funnel/filter on the top of the first or front-end form. After clicking the funnel/filter, notice you will be taken to the very first patient existing in your data set. It will say on the bottom bar 1 of n, where n is the number of patients in your database. If you want to search now, click on the field you want to use for searching, and click the binocular and fill in the requested information in the message box appeared afterward.

2. Keep in mind to fill in today's date, if you are updating a record!
3. Open only one application. If you accidentally opened two applications by double clicking, you will see the message stating: you can not save the record, and out of memory. You have to go back and close the leftmost application with the same name on the bottom bar by maximizing the leftmost application form and clicking on the X on the top of the screen.
4. Log into MSU by using pilot account (one per site). Log into MSU health team by using ht.msu.edu account.
5. You need to properly shut down your application, otherwise it will give you an error message when you turn it on next time. To properly shut down, you need to close all the applications, then go to "Start" on the left bottom of your screen. Scroll up to "Shut Down" and click it. You have to confirm that you want to shut down the computer. Wait until you see the message: it is safe to turn off your computer now. Then the laptop is automatically turned off. You can close it and store it properly.

Using E-Mail

You will be given an electronic mail (e-mail) account from which to send messages via the computer and modem to those on campus when you have questions. The program you will use for e-mail is called Microsoft Outlook. This section describes some basic steps to help you get started using the Outlook program. To send a message or to check your e-mail messages, you need to be connected to the server (i.e. have dialed in and be "on line"). This is described in another section of this manual.

Opening Outlook

When you turn on your computer, you will see an icon that says 'Outlook.' Double click on that icon. This will open Outlook and bring you to the main screen.

Sending a Message

1. On the top left cover, under where it says 'File,' you will see an icon that looks like an envelope and a piece of paper. Click once on this icon. This will open up another screen where the first line is 'To,' the next line is 'CC,' and the last line says 'Subject.' Under that is a large box of space.
2. First type the e-mail address of the person you are sending the message to in the 'To' space. If you wish to copy this message to someone, put their address in the 'CC' space. Write a one or two word description of what your message will be about in the 'Subject' space.
3. Type your message in the large box.
4. To actually "send" the message, you then click once on the 'Send' button on the top left. Your message will then be sent to the person.

Reading Messages

If you have received messages, they will appear on the screen in the large area on the right. This area lists 1) who the messages are from, 2) the subject, and 3) when they were sent.

1. To open a message, simply point your arrow to one of the messages and double click. This will open a screen with that message in it.
2. To go up and down, you may use the scroll at the right.
3. To close the message, simply click once on the "X" on the very top right corner of the message box.

Deleting Messages

To delete a message, simply highlight that message by clicking once on it. Then, click on the "X" button on the top middle (slightly to the left) button. To permanently delete an item, go to the right under where it says "Inbox." Use the scroll bar to scroll down to 'Deleted Item' and select that by clicking once. You may highlight the message you wish to delete and then push the Delete key on your computer. A message will pop up "Do you want to permanently delete?" and you select Yes.

Storing Messages in Folders

Under Inbox again there is a section called Inbox. Select this category by clicking once.

You may *create a folder* to hold messages of a certain type like 'Questions for Barb' or something. To do this:

1. Right click on the Inbox category. A list of choices will pop up.
2. Select by highlighting the choice 'Create Subfolder.' Another screen will pop up.
3. In the top box under 'Name' write the same of the subfolder and click on the 'OK' button.
4. It will ask you if want a shortcut? You may select yes or no. I usually select no.
5. Under the Inbox category, your subfolder will appear.

To retrieve a message from a subfolder, simply click on that subfolder and it will show you the messages saved in that subfolder.

To save a message to a subfolder, simply right click on a message to highlight it. A list of choices will appear.

Select the choice 'Move to folder.' A list of subfolders will appear. Select by highlighting the folder you wish to have it go in.

Reviewing Sent Messages

To review messages you have sent, simply go to the section under the main Inbox heading until you get to the end (scroll down) with a category called 'Sent Items.' Select this category and to the right a list of messages you have sent will appear.

Replying to a Message

Simply open the message, click on the 'Reply' button (top left) and then type in your message. When you have completed your message, click 'Send.' The message will go to who it came from.

Forwarding a Message

To send a message received by you from one person to another person, simply open the message and then click the 'Forward' button. Type the address of the person you are sending the message to in the 'To' line at the top and then add your message in the message box (if you choose). Again, click 'Send' when you are ready to send the message.

Mail and Schedule Web Access Overview

Use Microsoft Mail and Schedule Web Access to retrieve and work with data stored on a Microsoft Exchange Server computer using an Internet browser from any computer. You can log on to your personal account to read private e-mail, send messages, and schedule appointments. You may use this service anywhere in the world that you have an Internet connection.

Logging On

By using a web browser (Netscape or Internet Explorer) version 3.0 or higher you can access your MSU HealthTeam mail and schedule. Web address is: <http://ht.msu.edu/exchange>

Getting Started

1. In the **Log On** box, type your e-mail name (i.e. John.Doe or Fred.Flintstone).
2. Press ENTER or click the term **click here** below the **Log On** box.
3. A login box will pop up on the screen. In the **Username** box, type your network name. Your name must be entered in this format:

<domain>\<your network name>

Examples:

MSUFGP\doejo

MSUFGP\flintsfr




4. Press TAB to move to the **Password** box, and type your password.
5. Click **OK**.

Note If you use Microsoft Internet Explorer on a Macintosh, only your name must be entered in the **Username** box. Your domain name must be entered in the **Domain name** box.

Getting Help On-Line

The best resource for getting around the web mail client is to use the on-line help. To access the on-line help click on the blue question mark located towards the top of the window. It will default to the help for the section you are in (mail or schedule) but click on the 'Table of Contents' located in the upper right hand corner for a complete listing of help options.

Form I- Front-End Form

 	Patient Name (Last):	BLANK	
	(First):		
	Medical Record Number:		
	Date Of Birth:		
	bstructor's ID:		

Eligibility Criteria: Check One Item For Each Statement (1-5)

1. Patient gender is:	
2. Patient has been seen in last three years	
2a. Date of the very first visit to the FPC provid	
3. Patient birthday is between August 1, 1928 and July 31, 1960	
4. Breast health care provided by	
5. Active patient between 8/1/99 - 7/31/00	
5a. if there is documentation patient left practice before 7/31/00	
Other, specify	
Date of Documentation:	

Please remember to enter Question 2a, 5a and stamp the guideline and Summary Sheet

Meaning of Eligibility Code:

For site number 1-5:

- 1 = Eligible for abstract and insertio
- 2 = Eligible for insertion only
- 3 = Ineligible

For site number 6-9:

- 1 = Eligible for abstract
- 2 or 3 = Ineligible



For your reference, this is the old ECode assigned last year



Rules for Assigning Study ID:

Study ID will remain the same for all patients who are a part of last year's abstracted data . However, you will be required to specify their Eligibility code for the current year. Even if the Eligibility code for the current year changes, the Study ID remains the same. Your decision whether to proceed with abstraction for the current year will depend on the current ECode.

For patients who don't have a record in last year's database, please assign study ID according to the rules specified below

Study ID is a 6-digit number. The first digit is your site number. The second digit is the Eligibility code shown in the box above. The rest four digits are consecutive numbers starting 0001.

To assign study ID, please look in the box on the right, find out what was the last number assigned for that specific eligibility category, and use the next consecutive number.

For eligibility code =
For eligibility code =
For eligibility code =



Please assign study ID:

120000

Today's Date:

12/12/12



FOR INTERVENTION SITES (SITE NUMBER 1-5) ONLY:

For patients with Ecode = 1 or 2 only: please check if additional information was written on the Summary of Breast Care Sheet (one white sheet which can be found together with the guideline insertion) .

- ☐ Guideline Inserte ☐ Guideline Not Foun
- ☐ Summary Sheet Inserte ☐ Summary Sheet Not Foun
- ☐ Additional Information on Summary Sh
- ☐ No Additional Information on Summary Sh

HAVE YOU STAMPED GUIDELINES AND SUMMARY SHEET?

Search Add New Patient

Chart Review Form (Only For Eligible Patient)

Study ID: 20000

1. Date of Most Recent Office Visit Between 8/1/99 to 7/31/00 (MM/DD/YY):
2. Autocalculated Date For the Last Eligible Visit Within the Last 15 months (MM/DD/YY):
- 2a. Last Year's Autocalculated Date For the Last Eligible Visit Within the Last 15 months:
3. Total Number of Visits Within 15 Months, Including The Most Recent Visit:
4. Was A Breast Care Performed During Any of The Visits Within The 15 Months Period:
5. Personal/Family History Of Breast Cancer?

Search Add New Patient

Rule for filling in the age at diagnosis:

- 1) Fill in exact age when information is available
- 2) Fill in '777' if only known Pre-menopausal equal to or less than 50 years
- 3) Fill in '888' if only known Post-menopausal or greater than 50 years
- 4) Fill in '999' if no information is available

In Self?

No

Age:

Surgery/Reconstruction

- | | |
|--|--|
| <input type="checkbox"/> Complete Breast Removal | <input type="checkbox"/> Partial Breast Removal/Lumpectomy |
| <input type="checkbox"/> Prophylactic Implant | <input type="checkbox"/> Autologous Reconstitution |
| <input type="checkbox"/> Other, specify | |
| <input type="checkbox"/> Undocumented | |

Treatments (check all that apply)

- | | | |
|---|------------------------------------|---|
| <input type="checkbox"/> Chemotherapy | <input type="checkbox"/> Radiation | <input type="checkbox"/> Tamoxifen/Nolvadex |
| <input type="checkbox"/> Alternative medicine(s), specify | | |
| <input type="checkbox"/> Other, specify | | |
| <input type="checkbox"/> Undocumented | | |

In Mother

No

Age:

In Sister?

No

☐ Sister1 Age:

☐ Sister2 Age:

In Daughter?

No

☐ Daughter1 Age:

☐ Daughter2 Age:

In Other Relatives? No

Please specify:

BOX-A

Record information for patient's each visit when a breast care was performed. Start with the first visit when any breast care activity was recorded during that 15 months period. Click the button on the right to continue.

Continue to Record Visit Info

Go To First Patient


Go To Previous Patient

Go To Next Patient

Go To Last Patient

(Click Any of the Buttons Above to Navigate the Record)

Form II- Visit Entry

Add New Visit	Go To First Visit	Go To Previous Visit	Go To Next Visit	Go To Last Visit
	Study ID: 120000	Last Eligible Visit: 	Go Back to Front-End	

Please fill out Question 6 and Question 7 for every visit/call.

6. Date of Breast Care Activity Was Recorded: **1/1/11**

Type of Contact:

If this visit is about a test result, you can directly go to Test Result Form, without filling out CBE documentation

7. Purpose of this Visit/Call:

Specify:

[Go Directly to Test Result Form](#)

8. Who Performed Breast Care/Phone Consultation? (Check All That Apply)

☐ Resident Physician ☐ Faculty Physician ☐ Physician Assistant ☐ Nurse Practitioner ☐ Undocumented

Breast Care Provider1:

Breast Care Provider2:

9. Patient Presenting Symptoms/Signs (Check All That Apply)

Which breast(s) has presenting symptom?

If you don't know which breast, please record information in "Left Breast" category.

Left Breast:

Right Breast:

<input type="checkbox"/> None <input type="checkbox"/> Undocumented/Don't know	<input type="checkbox"/> None <input type="checkbox"/> Undocumented/Don't know
<input type="checkbox"/> Lump(s)/Mass(es)/Asymmetrical thickening	<input type="checkbox"/> Lump(s)/Mass(es)/Asymmetrical thickening
<input type="checkbox"/> Nipple Discharge	<input type="checkbox"/> Nipple Discharge
<input type="checkbox"/> Skin/Nipple change (check all that apply)	<input type="checkbox"/> Skin/Nipple change (check all that apply)
<input type="checkbox"/> Skin Dimpling <input type="checkbox"/> Erythema/Skin thickening	<input type="checkbox"/> Skin Dimpling <input type="checkbox"/> Erythema/Skin thickening
<input type="checkbox"/> Nipple Retraction <input type="checkbox"/> Nipple Scaling	<input type="checkbox"/> Nipple Retraction <input type="checkbox"/> Nipple Scaling
<input type="checkbox"/> Pain/Tenderness	<input type="checkbox"/> Pain/Tenderness
<input type="checkbox"/> Occult Mammographic Abnormality	<input type="checkbox"/> Occult Mammographic Abnormality
<input type="checkbox"/> Density(Nodule or Asymmetry)	<input type="checkbox"/> Density(Nodule or Asymmetry)
<input type="checkbox"/> Microcalcifications	<input type="checkbox"/> Microcalcifications
<input type="checkbox"/> Other, specify: 	<input type="checkbox"/> Other, specify:

10. CBE Documentation:

11. CBE Findings (Check All That Apply):

☐ Bilateral Implants

☐ Mastectomy, which breast?

☐ Previous abnormality resolved

☐ Lump/mass resolved ☐ Observational finding resolved ☐ Nipple discharge resolved ☐ Pain gone

☐ Normal/Symmetrical nodularity/Symmetrical fibrocystic (Fill Out Quality of CBE Documentation)

Quality of Written Description of CBE Documentation (Check All That Apply):

<input type="checkbox"/> Inspection, specify	Nipple Change	Undocumented	Breast Size/Shape	Undocumented
	Scar	Undocumented	Skin Change	Undocumented
<input type="checkbox"/> Palpation, specify	Fibrocystic Breast	Undocumented	Nodularity	Undocumented
	Mass(es)	Undocumented	Pain/tenderness	Undocumented
	Mastectomy site(s) free of mass Undocumented			
<input type="checkbox"/> Lymph node examination	Adenopathy/Axillary Node Undocumented			
<input type="checkbox"/> No specific documentation besides normal				
<input type="checkbox"/> Other, Specify: _____				

Abnormal: Which breast(s) has abnormal finding?

If you don't know which breast, please record information in "Left Breast" category.

Left Breast: _____ Right Breast: _____

Location:

☐ Lump(s)/Mass(es)/Asymmetric breast thickening/
Asymmetric Fibrocystic

Lump size:

Depth:

Hardness:

Mobility:

Shape:

Texture:

Additional Findings With Lumps (check all that appl

Skin Dimpling/Retraction Undocumented

Skin Erythema Undocumented

Skin Peau d'orange or
Skin Thickening Undocumented

Nipple Retraction Undocumented

Nipple Scaling Undocumented

Pain/Tenderness Undocumented

Fibrocystic Breast(s) Undocumented

Nipple Discharge Undocumented

☐ Other, Specify:

☐ Nipple Discharge With No Lum

Spontaneous?

Color

Unilateral or bilateral?

Single or multiple ducts

☐ Observational Findings With No Lump

☐ Skin dimpling/retraction

☐ Skin Erythema

☐ Skin Peau d'orange/Skin Thickening

☐ Nipple retraction

☐ Nipple scaling

☐ Pain

☐ Breast pain

☐ Chest wall pain

☐ Unspecified

☐ Other, specify:

Location:

☐ Lump(s)/mass(es)/Asymmetric breast thickening/
Asymmetric Fibrocystic

Lump size:

Depth:

Hardness:

Mobility:

Shape:

Texture:

Additional Findings With Lumps (check all that appl

Skin Dimpling/Retraction Undocumented

Skin Erythema Undocumented

Skin Peau d'orange or
Skin Thickening Undocumented

Nipple Retraction Undocumented

Nipple Scaling Undocumented

Pain/Tenderness Undocumented

Fibrocystic Breast(s) Undocumented

Nipple Discharge Undocumented

☐ Other, Specify:

☐ Nipple Discharge With No Lump

Spontaneous?

Color

Unilateral or bilateral?

Single or multiple ducts

☐ Observational Findings With No Lump

☐ Skin dimpling/retraction

☐ Skin Erythema

☐ Skin Peau d'orange/Skin Thickening

☐ Nipple retraction

☐ Nipple scaling

☐ Pain

☐ Breast pain

☐ Chest wall pain

☐ Unspecified

☐ Other, specify:

Quality of Written Description of CBE Documentation For Abnormal Findings (Check All That Apply):

<input type="checkbox"/> Drawing of abnormal finding				
<input type="checkbox"/> Inspection, specify	Nipple Change	Undocumented	Breast Size/Shape	Undocumented
	Scar	Undocumented	Skin Change	Undocumented
<input type="checkbox"/> Palpation, specify	Fibrocystic Breast	Undocumented	Nodularity	Undocumented
	Mass(es)	Undocumented	Pain/tenderness	Undocumented
<input type="checkbox"/> Lymph node examination				
Adenopathy/Axillary Node		Undocumented	Lymph Node Enlarged?	
<input type="checkbox"/> Other, Specify:				

☐ Click here if you changed anything about this visit entry, compared to last year's entry and briefly specify the

Go To Followup Form



Form III-Test Result Entry

Study ID: 120000

Date of the Visit: 1/1/11

Last Eligible Visit:

12. Mammogram Documentation:

1. Ordered/Recommended/Encouraged		Date:	
2. Mammogram Performed		Date:	
3. Results Obtained	Stamped/Documented?	Date:	
4. Results Reviewed By FPCP	Signed/Documented?	Date:	

13a. Mammogram Findings: Final Impressions

Which Breast?

If you don't know which breast, please record information in "Left Breast" category.

Left Breast:

Right Breast:

<input type="checkbox"/> Normal/No Finding Identified/Category I <input type="checkbox"/> Normal/Benign-appearing abnormality/Category II <input type="checkbox"/> Probably benign/possibly malignant, indeterminate /Category III <input type="checkbox"/> Suspicious for malignancy/Category IV <input type="checkbox"/> Malignant until proven otherwise/Category V <input type="checkbox"/> Other: Specify:	<input type="checkbox"/> Normal/No Finding Identified/Category I <input type="checkbox"/> Normal/Benign-appearing abnormality/Category II <input type="checkbox"/> Probably benign/possibly malignant, indeterminate /Category III <input type="checkbox"/> Suspicious for malignancy/Category IV <input type="checkbox"/> Malignant until proven otherwise/Category V <input type="checkbox"/> Other: Specify:
--	--

13b. Mammogram Findings: Description

Which Breast?

If you don't know which breast, please record information in "Left Breast" category.

Left Breast:

Right Breast:

☐ Asymmetric Breast: more in which bre

<input type="checkbox"/> Bilateral Implants <input type="checkbox"/> Radiolucent Breasts <input type="checkbox"/> Dense Breasts/Dense Nodular Breasts <input type="checkbox"/> Rounded density(ies), most likely cyst or fibroadeno <input type="checkbox"/> Irregular Density(ies) <input type="checkbox"/> Benign Appearing Calcifications <input type="checkbox"/> Suspicious Calcification <input type="checkbox"/> Calcified Fibroadenoma <input type="checkbox"/> Axillary Lymph Node <input type="checkbox"/> Other, specify	<input type="checkbox"/> Bilateral Implants <input type="checkbox"/> Radiolucent Breasts <input type="checkbox"/> Dense Breasts/Dense Nodular Breasts <input type="checkbox"/> Rounded densities, most likely cyst or fibroadenoma <input type="checkbox"/> Irregular Density(ies) <input type="checkbox"/> Benign Appearing Calcifications <input type="checkbox"/> Suspicious Calcification <input type="checkbox"/> Calcified Fibroadenoma <input type="checkbox"/> Axillary Lymph Node <input type="checkbox"/> Other, specify
--	---

13c. Mammogram Findings: Location For Category II and Up

Which Breast?

If you don't know which breast, please record information in "Left Breast" category.

IF AREA NOT SPECIFIED, check SCATTER/THROUGHOUT Breast category

Left Breast Location:

Right Breast Location:

<input type="checkbox"/> Upper Outer Quadrant <input type="checkbox"/> Lower Outer Quadrant <input type="checkbox"/> Upper Inner Quadrant <input type="checkbox"/> Lower Inner Quadrant <input type="checkbox"/> Lateral Breast <input type="checkbox"/> Medial Breast <input type="checkbox"/> Areolar/Nipple Area <input type="checkbox"/> Deep Against Chest Wall <input type="checkbox"/> Scattered/Throughout Breas <input type="checkbox"/> Other, specify _____	<input type="checkbox"/> Upper Outer Quadrant <input type="checkbox"/> Lower Outer Quadrant <input type="checkbox"/> Upper Inner Quadrant <input type="checkbox"/> Lower Inner Quadrant <input type="checkbox"/> Lateral Breast <input type="checkbox"/> Medial Breast <input type="checkbox"/> Areolar/Nipple Area <input type="checkbox"/> Deep Against Chest Wall <input type="checkbox"/> Scattered/Throughout Breas <input type="checkbox"/> Other, specify _____
---	---

14. Patient Notified of the Mammogram Findings?

Date of Notification:

15. Cyst-Fine Needle Aspiration (FNA)

Done by:

Date done:

☐ Mass resolved/fluid not blood ☐ Fluid blood

☐ Residual Mass

☐ Other, specify: _____

☐ Sent Fluid to Cytology

Results Obtained

Stamped/Documented?

Date:

Results Reviewed By FPCP

Signed/Documented?

Date:

Cytology Results:

☐ Insufficient/Hypocellular/Apocrine Cell

☐ Benign/Fibrocystic/Apocrine Cells

☐ Atypical cells

☐ Suspicious for malignancy

☐ Malignant

☐ Other, specify: _____

16. Patient Notified of the FNA Findings From Cytology?

Date of Notification:

17. Solid Mass-Fine Needle Aspiration Biopsy (FNAB)

Done by:

Date done:

☐ Specimen Submitted For Analysis

Results Obtained

Stamped/Documented?

Date:

Results Reviewed By FPCP

Signed/Documented?

Date:

Pathology Results:

☐ Insufficient/Hypocellular

☐ Benign/Fibrocystic

☐ Atypical cells

☐ Suspicious for malignancy

☐ Malignant

☐ Other, specify: _____

18. Patient Notified of the FNAB Findings From Path Report?

Date of Notification:

19. Ultrasound Findings:

Ordered by:

Date done:

Results Obtained

Stamped/Documented?

Date:

Results Reviewed By FPCP

Signed/Documented?

Date:

- ☐ Negative finding ☐ Simple cyst(s) ☐ Solid mass(es) or complex cyst(s)
☐ Other, specify: _____

20. Patient Notified of the Ultrasound Findings?

Date of Notification: _____

21. Image-Guided Biopsy/Open Biopsy Results:

Date done: _____

Results Received

Stamped/Documented?

Date: _____

Results Reviewed By FPCP

Signed/Documented?

Date: _____

Open Biopsy Findings(check all that apply):

- | | |
|---|--|
| <input type="checkbox"/> Benign/No Evidence of Malignancy | <input type="checkbox"/> Ductal Carcinoma in situ |
| <input type="checkbox"/> Benign/Fibrocystic Changes | <input type="checkbox"/> Lobular Carcinoma in situ |
| <input type="checkbox"/> Benign/Fat Necrosis | <input type="checkbox"/> Atypical Hyperplasi |
| <input type="checkbox"/> Benign/Lipoma | <input type="checkbox"/> Invasive Ductal Carcinom |
| <input type="checkbox"/> Benign/Fibroadenoma | <input type="checkbox"/> Invasive Lobular Carcinom |
| <input type="checkbox"/> Other, specify _____ | |

- ☐ Click here if you changed anything about this visit entry, compared to last year's entry and briefly specify the

Go To Followup
Form

Form IV-Follow-up Entry

StudyID: [REDACTED] Date of Visit: [REDACTED] Last Eligible Visit: [REDACTED]

23. Recommended Follow-Up(s) (Check All That Apply)

☐ **Undocumented**

Follow-up for Normal CBE and Mammogram (or One of Them Undocumented):

<input type="checkbox"/> Routine Screening	<input type="checkbox"/> 12 Month CBE	<input type="checkbox"/> 12 Month Mammogram
<input type="checkbox"/> Following ACS Guidelines	<input type="checkbox"/> Following Other Guidelines	specify: _____
Recommended by: _____		Comments: _____

Follow-up for Specific Abnormalities:

Follow-up Common To Any Abnormalities:

Breast Mass/Asymetry Initial Approach:

- ☐ CBE at better phase cycle (3-10 days)
☐ Fine Needle Aspiration for Cyst

If Known Breast Cyst:

- ☐ Send Fluid to Cytology ☐ Reaspiration
☐ (How many) month CBE

If Known Solid Mass:

- ☐ Fine Needle Aspiration Biopsy
☐ Specimen Submitted for Analy
☐ Repeat aspiration
☐ Clinical Followup Every 3 Months for 1 Year

For Nipple Discharge:

- ☐ Endocrine work-up

For Skin/Nipple Changes on Observation:

- ☐ 2 weeks antibiotics ☐ Skin Biopsy
☐ 2 weeks topical hydrocortisone

For Breast pain:

- ☐ Eliminate Caffeine
☐ Adjust Estrogen Dose
☐ Local Anesthetic Injectio
☐ Primrose Oil How Many Months
☐ Reassurance and CBE within 3-6 months if pain persist
☐ Supportive Brassiere
☐ Over-the-counter Analgesics
☐ Danazol, Bromocriptine

For Occult Mammographic Abnormality:

- ☐ Radiologic Biopsy/Image-Guided Biopsy

Recommended by:

- ☐ Call if Problem Worsens

- ☐ Routine Screening

Recom. by:

Immediate Mammogram Workup:

- ☐ Regular Mammogram
☐ Extra Mammogram Views
☐ Cone or Spot Compressio
☐ Magnification Views

Recom. by:

Interval Followup:

(How many) month mammogra

(How many) month CBE

Recom. by:

- ☐ Ultrasound

Recom. by:

- ☐ Surgical Referral

Recom. by:

- ☐ Undocumented

Other Recommendations Or Comments Concerning Abnormality(ies):

General Comments About This Visit:

Assessment/Recommended Follow-up From Surgeon's Letter

1. Letter Written	Date:	
2. Letter Received	Stamped/Documented?	Date:
3. Letter Reviewed by FPCP	Signed/Documented?	Date:

Assessment

Followup

<input type="checkbox"/> Referral Diagnosis Not Confirmed <input type="checkbox"/> Referral Diagnosis Confirmed <input type="checkbox"/> Additional/New findings <input type="checkbox"/> Further Tests Recommended/Done By Surgeon, check all that apply <input type="checkbox"/> Immediate Mammogra <input type="checkbox"/> Interval Mammogram, how lon <input type="text"/> <input type="checkbox"/> Interval CBE, how long <input type="text"/> <input type="checkbox"/> Ultrasound <input type="checkbox"/> FNA <input type="checkbox"/> FNAB <input type="checkbox"/> Radiological/Image Guided Biopsy <input type="checkbox"/> Open Biopsy Evidence of Malignancy <input type="text" value="No"/> <input type="checkbox"/> Previous Abnormality Resolved <input type="checkbox"/> Current Abnormality Resolve <input type="checkbox"/> Other Comments From Surgeon's Let	<input type="checkbox"/> No Further Workup Required <input type="checkbox"/> Followup In Primary Care Office <input type="checkbox"/> Followup In Surgeon's Office
---	--

☐ Click here if you changed anything about this visit entry, compared to last year's entry and briefly specify the

Go Back to
Form II

Go Back to
Form III

Add New
Visit

Search/ Add
New patient

Quality Assurance

What is meant by Quality Assurance?

Quality assurance is checking to make sure that what you are abstracting accurately reflects what is truly in the medical record. It is important that we determine your accuracy to make sure that the data being collected truly reflects what has been documented in the medical record.

What is Involved in Quality Assurance?

At two points during the early and middle point of your auditing time, Barbara Given, PhD, RN, or her designee, will visit your program site. She will select randomly 10 medical records that you have audited. She will then audit these records on her own without looking at how you have audited the record. A comparison will be made between the data collected when you audited the records and when she audited the records. A statistic called a Kappa will be used to determine the degree of consistency between the two sets of collected data. If there is low consistency, this may indicate a problem with accuracy.

What happens if I am found to have low accuracy?

The quality assurance auditor will then look over the cases and compare. Clarifications as to how to handle certain cases will be discussed. This process is called remediation. The quality assurance auditor will then return at a later time to do another quality assurance comparison. If there continues to be a problem with accuracy of audited information, other steps may need to be taken.

What do I do If I have questions regarding how to audit a record?

Contact Barbara Given, PhD, RN. The best way to contact her is by email. Her address is bgiven@msu.edu. Keep in mind that Dr. Given has MANY responsibilities. However, your questions are important. Just remember it might take a few days for her to return your email with a response. Sometimes it might mean that she has to ask someone else what the answer is. Simply keep track of your questions and continue auditing. Return to answer that question at a later time when you receive your answer.

If it is a particularly urgent question, you may try calling her at (517) 432-4326 or Jodi Holtrop, PhD, at (517) 353-3544 ext. 432.

What will be happening at each site?

At both intervention and control sites - Nurse abstractors will be performing chart audits on the charts of female active patients age 40-70 years of age. These nurses will be regularly sending information to MSU via the use of a laptop computer, which will be kept at the site for the duration of the project. Nurses will be abstracting charts during August through October 1999 and same months in 2000.

Intervention sites – Health care providers will receive the one day training in the summer of 1999 and are encouraged to use the chart reminder and follow-up form during the year after training. This chart reminder and follow-up form will be included in charts.

Control sites – Health care providers will receive a one day training (if they choose) in the summer of 2000 and have the option to use the chart reminder and follow-up system at that time.

This project is funded by the Department of Defense.

APPENDIX 6

Patient Instructor Training Information

CONSENT FORM FOR PATIENT INSTRUCTORS

I, _____, consent to participate as a patient instructor in this training course to demonstrate clinical breast examination techniques to Physicians, Advanced Practice Nurses and Physician Assistants.

As part of the course, I will have an initial screening examination by a licensed healthcare professional and complete a short health history. The faculty member will help me understand the type of feedback and information I should discuss with the course participants assigned to me. This examination is for the purpose of this training course only and not for personal screening or diagnostic purposes. I understand that the clinical breast examination techniques being used by participants may not detect all lumps or irregularities in my breasts and that this examination does not substitute for an examination by my usual health care provider. Should any of the course faculty or participants find or suspect any new irregularities or lumps in my breasts, it is my responsibility to bring it to the attention of my usual healthcare provider.

I will be interviewed about my breast health history and have my breasts examined in a private room by one course participant for several sessions using techniques of visual observation and manual palpation. I have been informed that repeated exams may cause some breast tenderness and that if the tenderness persists for more than a few days I should consult with my usual healthcare provider.

I have been given the opportunity to ask questions about the examination technique and the course, and I feel I understand the purposes and my role as a patient instructor.

Occasionally facilities allow for observation of the examination by other course instructors or selected participants through a one-way mirror. If this situation is planned, I will be told in advance who will be observing. I will __, will not __ allow observation. _____
(Initials)

Signature _____ Date: _____

Witness Signature _____ Date: _____

ESSENTIALS OF BREAST CARE

PATIENT INSTRUCTOR SCREENING HEALTH HISTORY

Thank you for agreeing to be a patient instructor for this course. Please answer the following questions and discuss the information with the course faculty and the selected participants who will be examining you. All of your answers are confidential.

Name _____ Age _____ Today's Date ____/____/____

1. Have you ever had any of the following examinations of your breast?

Physical breast exam by a doctor or nurse:

- ☐ no
- ☐ yes most recent exam was _____
results: ☐normal ☐abnormal ☐don't know
other _____
- ☐ don't know

Mammogram-an x ray of your breasts (different from a chest x ray):

- ☐ no
- ☐ yes most recent one was: results: ☐normal ☐abnormal ☐don't know
other _____
- ☐ don't know

Other tests on your breasts (ultrasound, fine needle aspiration, biopsy):

- ☐ no
- ☐ yes which breast(s)? __right__ left
test done: _____
how long ago? _____
results: ☐normal ☐abnormal ☐don't know
other _____
- ☐ don't know

2. Do you ever check your own breasts (breast self-exam)?

- ☐ no
- ☐ yes About how often? _____
How did you learn to do a breast self-exam? (check all that apply)
☐course ☐healthcare provider ☐video ☐pamphlet ☐self-taught

3. Are you currently having any breast tenderness?

- ☐ no
- ☐ yes is it ☐premenstrual ☐from hormones ☐other _____?

ESSENTIALS OF BREAST CARE

4. Have any members in your immediate family (sister, mother, daughter) had breast cancer? If you are adopted and don't know, please check that box.

- ☐ no
- ☐ don't know
- ☐ adopted-don't know
- ☐ yes

If so, which family member(s) had breast cancer and note if they are living or deceased.

Relationship

_____	<input type="checkbox"/> living	<input type="checkbox"/> deceased
_____	<input type="checkbox"/> living	<input type="checkbox"/> deceased
_____	<input type="checkbox"/> living	<input type="checkbox"/> deceased

5. How would you rate your risk for developing breast cancer sometime during your lifetime?

- ☐ low
- ☐ medium
- ☐ high
- ☐ don't know

6. Do you have any concern about your breasts you would like the faculty or participants to know?

ESSENTIALS of BREAST CARE

PATIENT INSTRUCTOR RESPONSIBILITIES

I. Attend an initial orientation session and receive a clinical breast examination by a licensed health care professional.

- A. Review packet of orientation materials.
- B. Complete the consent form and health history after they are explained to you.
- C. View a video on clinical breast examination.
- D. Learn how to:
 - 1. Trace the area of breast tissue (perimeter) on yourself, noting landmarks of anatomy.
 - 2. Answer questions about your health history based on your responses on the history form.
 - 3. Provide verbal feedback to course participants on selected communication skills.
 - 4. Provide verbal feedback to course participants on their palpation pressures during the examination, noting if/when pressures are uncomfortable.
 - 5. Recognize your own breast tissue characteristics, and provide feedback to participants on their assessment.

II. During the course:

- A. Arrive at the appointed time and commit to several examinations per session.
- B. Pretest:
 - 1. complete the evaluation form labeled "Pretest" after being examined
 - 2. do not discuss the examination technique with the learner
- C. Practice session
 - 1. provide feedback to the learner
 - 2. not all learners will have this session
- D. Posttest:
 - 1. complete the evaluation form labeled "Posttest" after being examined
 - 2. do not discuss the examination technique with the learner
- E. During all three components
 - 1. clarify information about your health history
 - 2. evaluate their skills in palpation, communication and patient education.

III. Tips for the day of the examination

- A. Wear a two-piece outfit since you only need to remove clothing above the waist.
- B. Since there will be periods when you are waiting for your session, you might want to bring something to read or do (for example, knitting).
- C. Sometimes the exam rooms are cool, so bring a sweater or jacket- we will try to provide blankets.

Scoring Instructions

- Start timing when the participant begins palpating
- Check the pattern of search used
- Place an "S" to indicate start of pattern
- Place a tick mark in each square that represents an area the participant palpates, following the pattern that is used
- Place an "F" at the finish point
- If the participant goes back to cover an area that may have been missed or not done well, indicate with an "x"
- Proficiency checklist: mark performance for each item, noting comments for feedback (only during the practice session)
- When the participant is finished, record the time.

Feedback (During the practice sessions only)

- The patient instructor can share observations with the participant during the practice session.
- Point out areas on the grid that may have been missed.
- Discuss their performance on each of the Ps and on the sequential depths of pressure.

APPENDIX 7

Workshop Outline of the Day

Essentials of Breast Care for Primary Care Physicians
Outline of the Day

7:30 – 7:45 Refreshments, Registration

7:45-7:50 Introductions

7:50 –8:10 Consent form and Pre-test

8:10-12:10 Lecture content (includes 2 short breaks)

12:10 – 1:15 Lunch with practice using the GAIL model

1:15 – 2:15 3 – 20 minute stations:

Station 1 – Patient models

Station 2 – Silicone breast models

Station 3 - Post-test

Blue Group – Start with station 1, then 2, then 3

Red Group – Start with station 2, then 3, then 1

Green Group – Start with station 3, then 1, then 2

2:15 – 3:30 Additional teaching including video

3:30 – 3:40 Break w/ refreshments

3:40 – 4:40 3 – 20 minute stations:

Station 1 – Patient models

Station 2 – Silicone breast models

Station 3 - GAIL Model

Blue Group – Start with station 1, then 2, then 3

Red Group – Start with station 2, then 3, then 1

Green Group – Start with station 3, then 1, then 2

4:40 – 4:50 Complete CME Evaluation and Receive Certificate

4:50 - 5:10 Discussion of results and feedback

End of Training

Per ACCME Standards of Commercial Support, we are obliged to tell you that the presenters do not have any significant financial relationships that create, or may be perceived as creating, a conflict related to this educational activity.

APPENDIX 8

Patient Instructor Evaluation Form

ESSENTIALS of BREAST CARE

Pre-Test

DATE _____
EXAMINER ID _____
PATIENT INSTRUCTOR _____

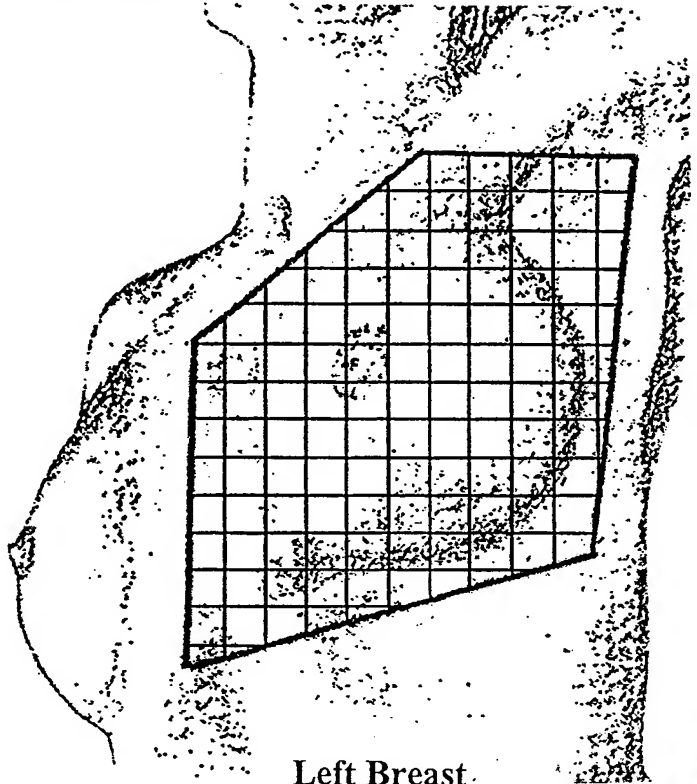
LEFT BREAST EXAMINATION TIME _____
minutes

DOCTOR/PATIENT ENCOUNTER TIME _____
minutes

Scoring:

- ☐ Mark "S" at start
- ☐ Mark "F" at finish
- ☐ Thorough exam (ALL areas covered)
- ☐ Mark X for each area NOT palpated

**PLEASE DO NOT
GIVE FEEDBACK!**



Left Breast

COMMUNICATION

- ☐ Introduces self
- ☐ Establishes rapport
- ☐ Checks on comfort
- ☐ Elicits/responds to questions/concerns

POSITIONS

Patient Sitting

Visual inspection

- ☐ arms at sides
- ☐ arms above head
- ☐ pressure on hips with hands

Palpates lymph nodes

- ☐ supraclavicular
- ☐ infraclavicular
- ☐ axillary

Patient Supine

- ☐ Centralizes each breast
- ☐ Arm behind or at right angle to head

PERIMETER

- ☐ Palpates entire area within perimeter

PATTERN OF SEARCH

- ☐ Uses consistent pattern
 - ☐ vertical
 - ☐ wedge
 - ☐ circular
 - ☐ other
- ☐ Adequate amount of overlap

PALPATION

- ☐ 3 middle fingers
- ☐ Pads, not tips
- ☐ Hand bowed upward
- ☐ Sliding motion, doesn't lift fingers
- ☐ Overlapping, dime size circles

PRESSURE

- ☐ 3 sequential depths
_____ superficial _____ medium _____ deep

PATIENT EDUCATION

- ☐ Points out anatomic landmarks
- ☐ Reviews early detection triad intervals
 - ☐ Monthly BSE
 - ☐ Annual CBE
 - ☐ Mammogram every 1-2 years
- ☐ Checks for understanding and agreement

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ESSENTIALS of BREAST CARE

DATE _____
EXAMINER ID _____
PATIENT INSTRUCTOR _____

RIGHT BREAST EXAMINATION TIME
_____ minutes

PATIENT DOCTOR ENCOUNTER TIME
_____ minutes

Scoring:

- ☐ Mark "S" at start
- ☐ Mark "F" at finish
- ☐ Thorough exam (ALL areas covered)
- ☐ Mark X for each area NOT palpated

**PLEASE DO NOT
GIVE FEEDBACK!**

COMMUNICATION

- ☐ Introduces self
- ☐ Establishes rapport
- ☐ Checks on comfort
- ☐ Elicits/responds to questions/concerns

POSITIONS

Patient Sitting

Visual inspection

- ☐ arms at sides
- ☐ arms above head
- ☐ pressure on hips with hands

Palpates lymph nodes

- ☐ supraclavicular
- ☐ infraclavicular
- ☐ axillary

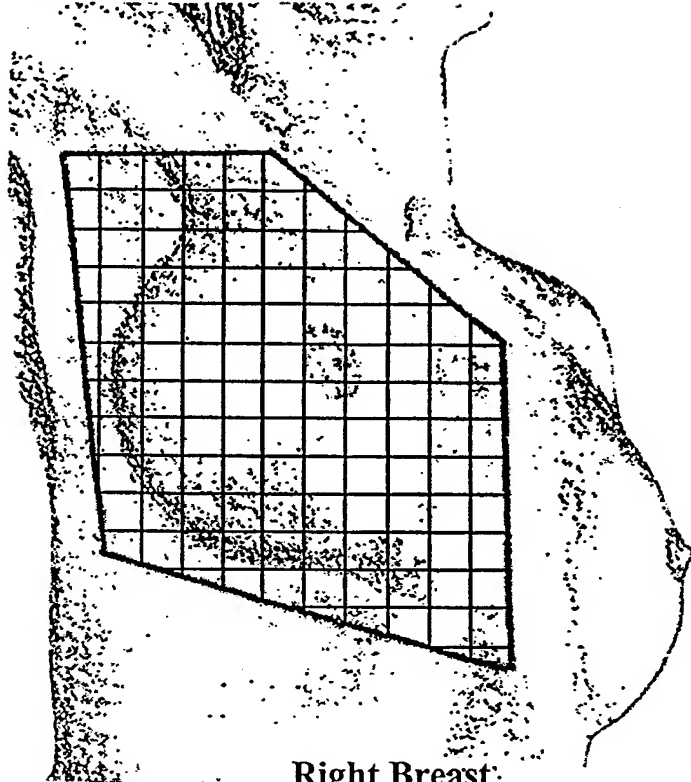
Patient Supine

- ☐ Centralizes each breast
- ☐ Arm behind or at right angle to head

PERIMETER

- ☐ Palpates entire area within perimeter

Pre-Test



Right Breast

PATTERN OF SEARCH

- ☐ Uses consistent pattern
 - ☐ vertical
 - ☐ wedge
 - ☐ circular
 - ☐ other
- ☐ Adequate amount of overlap

PALPATION

- ☐ 3 middle fingers
- ☐ Pads, not tips
- ☐ Hand bowed upward
- ☐ Sliding motion, doesn't lift fingers
- ☐ Overlapping, dime size circles

PRESSURE

- ☐ 3 sequential depths
_____ superficial _____ medium _____ deep

PATIENT EDUCATION

- ☐ Points out anatomic landmarks
- ☐ Reviews early detection triad intervals
 - ☐ Monthly BSE
 - ☐ Annual CBE
 - ☐ Mammogram every 1-2 years
- ☐ Checks for understanding and agreement

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ESSENTIALS of BREAST CARE

Post-Test

DATE _____
EXAMINER ID _____
PATIENT INSTRUCTOR _____

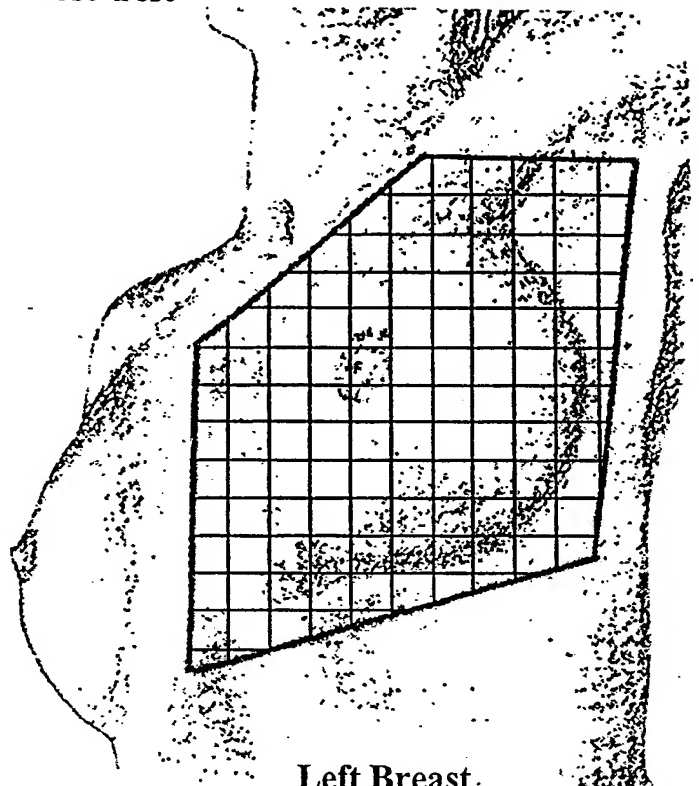
LEFT BREAST EXAMINATION TIME
_____ minutes

DOCTOR/PATIENT ENCOUNTER TIME
_____ minutes

Scoring:

- ☐ Mark "S" at start
- ☐ Mark "F" at finish
- ☐ Thorough exam (ALL areas covered)
- ☐ Mark X for each area NOT palpated

**Remember: Give Feedback
AFTER EXAM, not during !**



Left Breast

COMMUNICATION

- ☐ Introduces self
- ☐ Establishes rapport
- ☐ Checks on comfort
- ☐ Elicits/responds to questions/concerns

POSITIONS

Patient Sitting

Visual inspection

- ☐ arms at sides
- ☐ arms above head
- ☐ pressure on hips with hands

Palpates lymph nodes

- ☐ supraclavicular
- ☐ infraclavicular
- ☐ axillary

Patient Supine

- ☐ Centralizes each breast
- ☐ Arm behind or at right angle to head

PERIMETER

- ☐ Palpates entire area within perimeter

PATTERN OF SEARCH

- ☐ Uses consistent pattern
 - ☐ vertical
 - ☐ wedge
 - ☐ circular
 - ☐ other
- ☐ Adequate amount of overlap

PALPATION

- ☐ 3 middle fingers
- ☐ Pads, not tips
- ☐ Hand bowed upward
- ☐ Sliding motion, doesn't lift fingers
- ☐ Overlapping, dime size circles

PRESSURE

- ☐ 3 sequential depths
_____ superficial _____ medium _____ deep

PATIENT EDUCATION

- ☐ Points out anatomic landmarks
- ☐ Reviews early detection triad intervals
 - ☐ Monthly BSE
 - ☐ Annual CBE
 - ☐ Mammogram every 1-2 years
- ☐ Checks for understanding and agreement

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ESSENTIALS of BREAST CARE

DATE _____
EXAMINER ID _____
PATIENT INSTRUCTOR _____

RIGHT BREAST EXAMINATION TIME
_____ minutes

DOCTOR/PATIENT ENCOUNTER TIME
_____ minutes

Scoring:

- ☐ Mark "S" at start
- ☐ Mark "F" at finish
- ☐ Thorough exam (ALL areas covered)
- ☐ X for each area NOT palpated

**Remember: Give Feedback
AFTER EXAM, not during!**

COMMUNICATION

- ☐ Introduces self
- ☐ Establishes rapport
- ☐ Checks on comfort
- ☐ Elicits/responds to questions/concerns

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Visual inspection

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Palpates lymph nodes

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- ☐ infraclavicular
- ☐ axillary

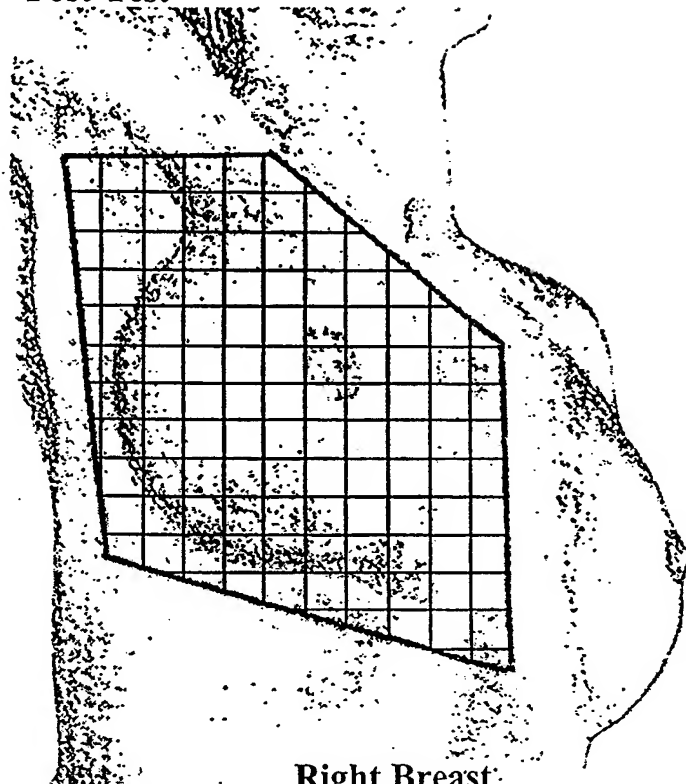
Patient Supine

- ☐ Centralizes each breast
- ☐ Arm behind or at right angle to head

PERIMETER

- ☐ Palpates entire area within perimeter

Post-Test



Right Breast

PATTERN OF SEARCH

- ☐ Uses consistent pattern
 - ☐ vertical
 - ☐ wedge
 - ☐ circular
 - ☐ other
- ☐ Adequate amount of overlap

PALPATION

- ☐ 3 middle fingers
- ☐ Pads, not tips
- ☐ Hand bowed upward
- ☐ Sliding motion, doesn't lift fingers
- ☐ Overlapping, dime size circles

PRESSURE

- ☐ 3 sequential depths
_____ superficial _____ medium _____ deep

PATIENT EDUCATION

- ☐ Points out anatomic landmarks
- ☐ Reviews early detection triad intervals
 - ☐ Monthly BSE
 - ☐ Annual CBE
 - ☐ Mammogram every 1-2 years
- ☐ Checks for understanding and agreement

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APPENDIX 9

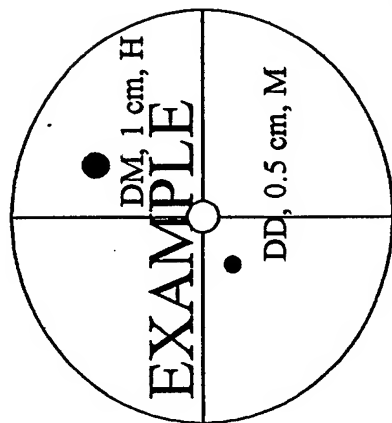
Silicone Breast Model Evaluation Form

Essentials of Breast Care

Clinical Breast Examination Form

Pre-test Silicone Breast Models

These breasts simulate the breast tissue of a 50 year old woman.



Site _____

Date ____/____/____

INSTRUCTIONS: Draw each lump in the appropriate location and indicate in the following order:

1. Depth: Medium (DM), 2. Size: 0.3 cm
Deep (DD) 0.5 cm
1.0 cm
3. Hardness: Hard (H)
Medium (M)
Soft (S)

1

Table 1

2

D _____
F.P. _____

D _____
F.P. _____

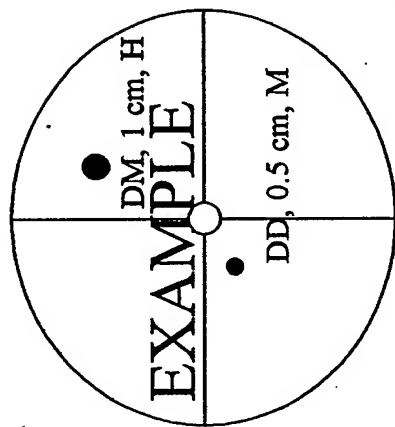
Total D _____ Total F.P. _____ Sensitivity _____ % Specificity _____ %

Essentials of Breast Care

Clinical Breast Examination Form

Pre-test Silicone Breast Models

These breasts simulate the breast tissue of a 50 year old woman.



Site _____

Date ____/____/____

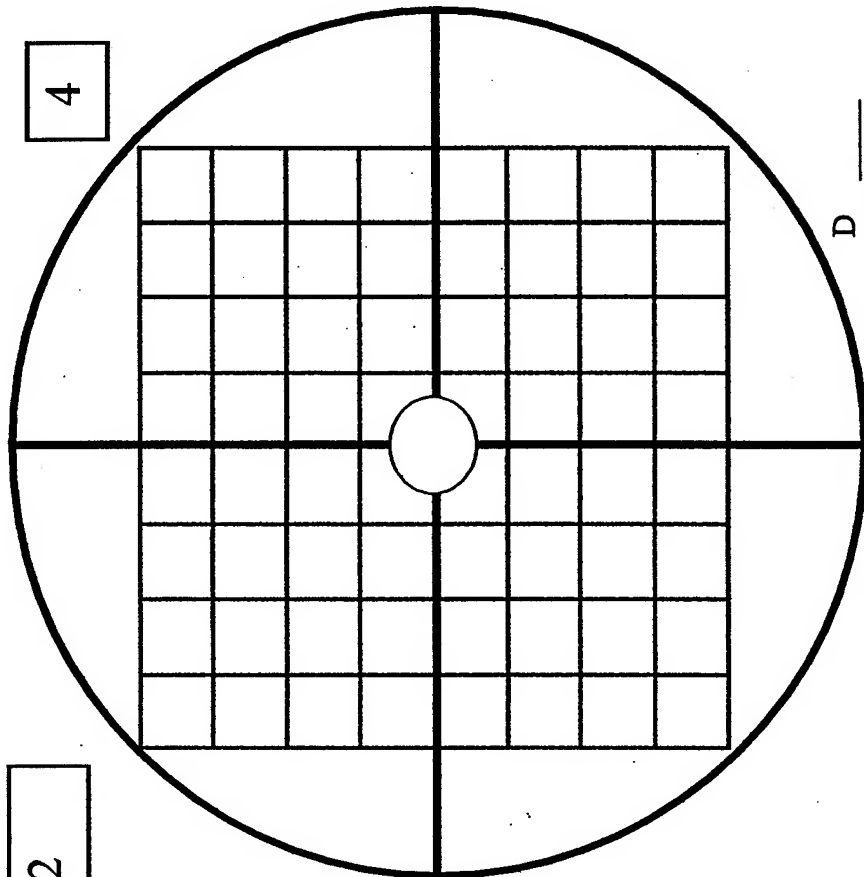
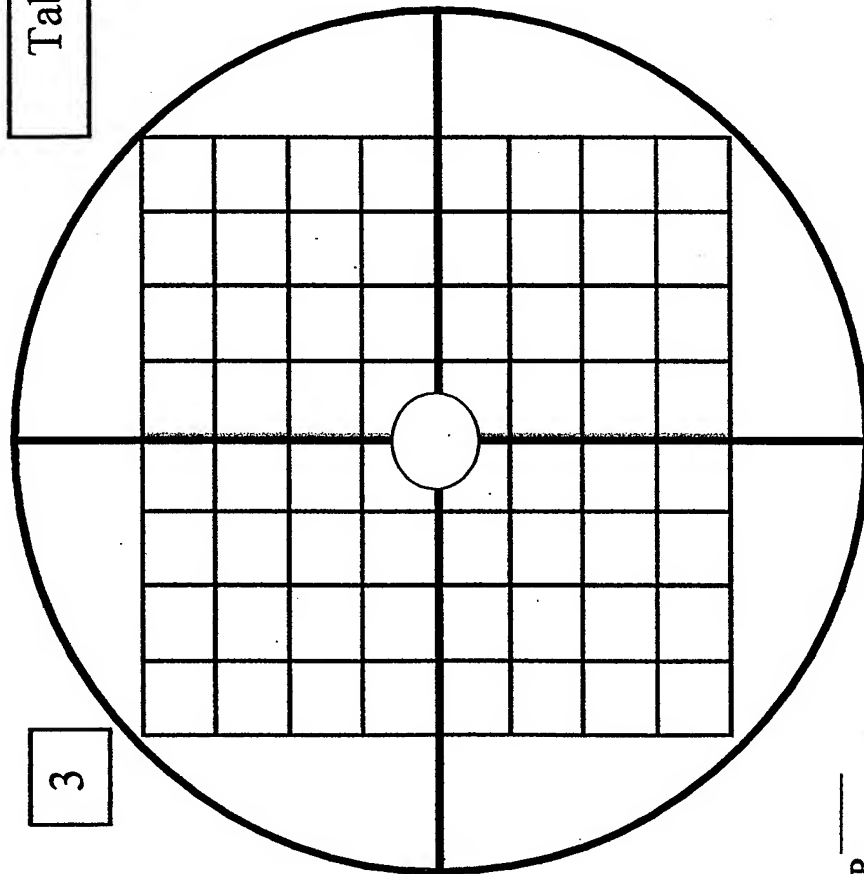
INSTRUCTIONS: Draw each lump in the appropriate location and indicate in the following order:

1. Depth: Medium (DM), 2. Size: 0.3 cm
Deep (DD) 0.5 cm
1.0 cm
3. Hardness: Hard (H)
Medium (M)
Soft (S)

3

Table 2

4



D _____
F.P. _____

Total D _____ Total F.P. _____ Sensitivity _____ % Specificity _____ %

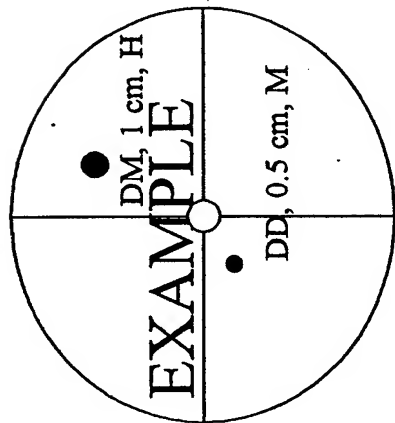
D _____
F.P. _____

Essentials of Breast Care

Clinical Breast Examination Form

Pre-test Silicone Breast Models

These breasts simulate the breast tissue of a 50 year old woman.



Site _____

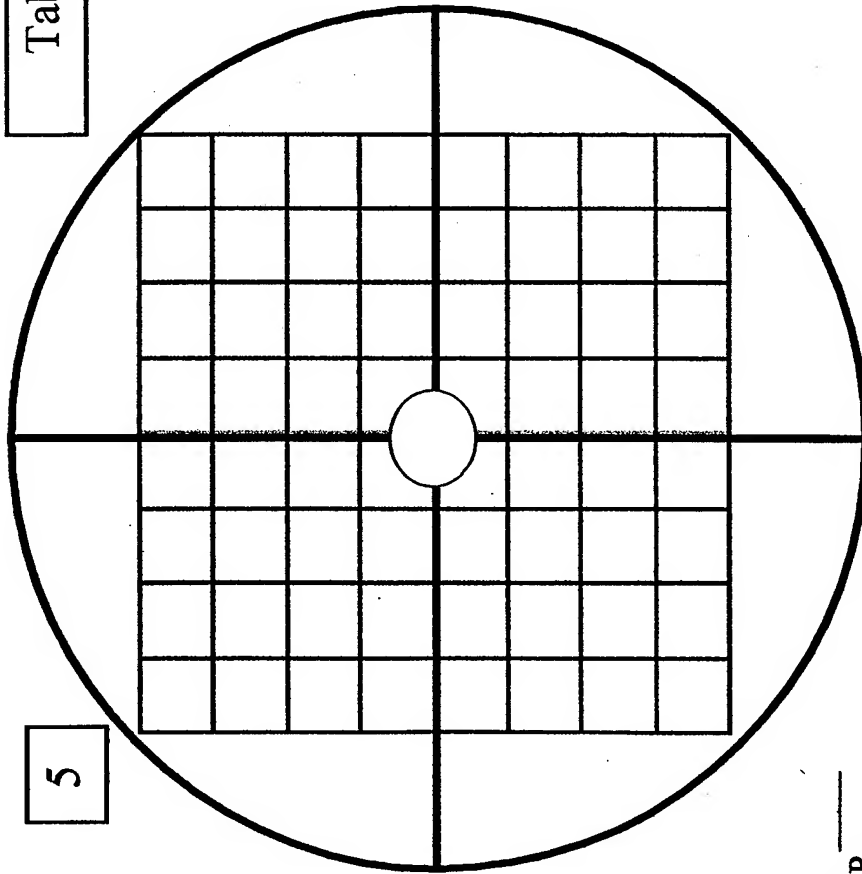
Date ____/____/____

INSTRUCTIONS: Draw each lump in the appropriate location and indicate in the following order:

1. Depth: Medium (DM), 2. Size: 0.3 cm
Deep (DD) 0.5 cm
1.0 cm
3. Hardness: Hard (H)
Medium (M)
Soft (S)

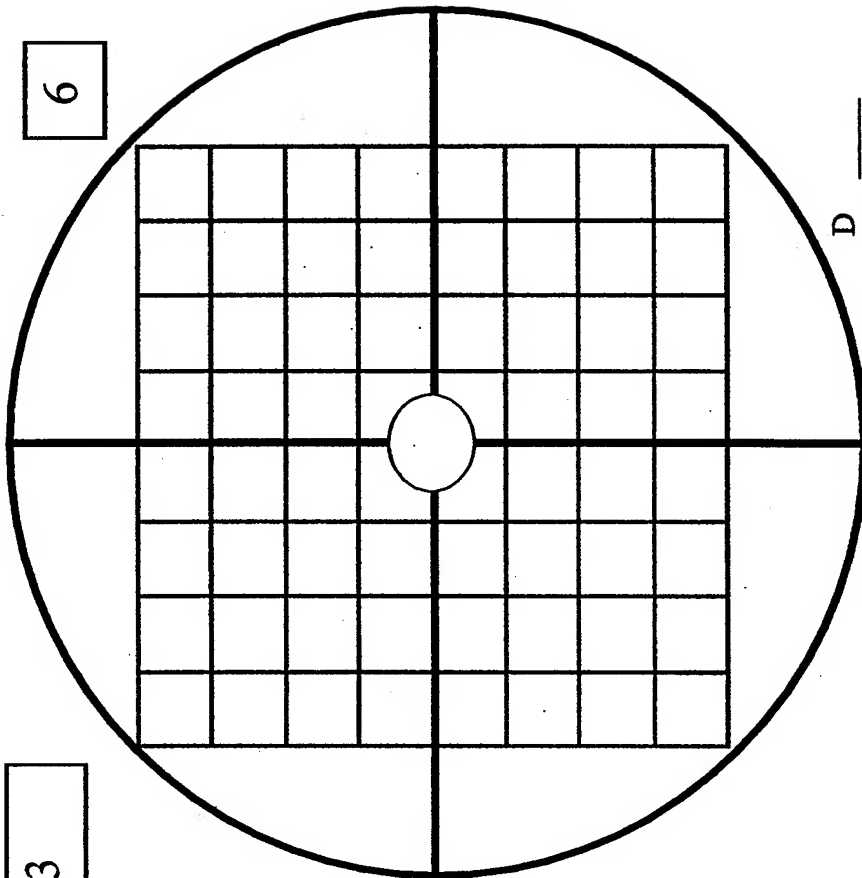
Table 3

5



D _____
F.P. _____

6



D _____
F.P. _____

Total D _____ Total F.P. _____ Sensitivity _____ % Specificity _____ %

APPENDIX 10

Knowledge, Attitude and Behavior Scale



ESSENTIALS OF BREAST CARE

PHYSICIAN'S SURVEY: *PRE*

FP Residency (Site) _____ ID _____

AUTHORS:

Janet R. Osuch, MD, FACS
Henry C. Barry, MD, MS
Thomas J. Zuber, MD

Principal Investigator:

Dorothy R. Pathak, PhD, MS

February 2001

Essentials of Breast Care

Physician Survey: PRE Educational Component

Choose the best answer:

1. In the United States Breast Cancer occurs:
 - a. In over 170,000 women and 1,000 men each year
 - b. Most commonly per 100,000 women in the age group 55-60 years old
 - c. In fewer than 5,000 women under the age of 50, annually
 - d. In one in eight women at age 50
2. When Dr. Jones examines a pre-menopausal woman, the best time to perform a clinical breast examination is:
 - a. During the luteal phase of her menstrual cycle.
 - b. At the onset of menses.
 - c. Days 3-10 of her menstrual cycle.
 - d. The timing of the exam doesn't matter.
3. Regarding the risk factors for breast cancer, which of the following is TRUE?
 - a. Seventy-five percent of women diagnosed with breast cancer have no risk factors other than age and gender.
 - b. A 75-year old woman is at lower risk than a 65-year old woman.
 - c. The majority of women diagnosed with breast cancer have a family history of the disease.
 - d. Most women with fibrocystic changes have an increased risk.
4. A 52-year old woman has screening mammography. A small group of microcalcifications are found. The next step in her management should be:
 - a. A 6 month follow-up mammogram
 - b. An ultrasound examination
 - c. Cone compression mammography
 - d. Magnification mammographic views
5. All of the following statements about "abnormal" screening mammography interpretations are true EXCEPT:
 - a. 35% of screening mammograms are termed abnormal and require patient "call back" for additional diagnostic views.
 - b. Current follow-up of reported abnormal mammograms is sub-optimal because women often are not notified of the results.
 - c. Following the recommendation for additional imaging studies is cost-effective and limits unnecessary specialty referral.
 - d. Over 50% of women will have the abnormality resolved by further diagnostic studies.

6. A 38-year old woman who has no known risk factors for breast cancer discovers a right breast mass on breast self-examination. On CBE, a 1 cm. mass in the upper outer quadrant of the right breast is found. You interpret the mass as benign. All of the following are appropriate management options EXCEPT:
- Have her return 3-10 days after the onset of her next menstrual cycle for a repeat breast examination.
 - A surgical referral
 - A fine needle aspiration
 - Reassurance
7. The single most important duty of a clinician when presented with a patient with a breast mass is:
- To order a bilateral mammogram
 - To document the location of the mass in the chart and make timely referral to a breast specialist
 - To inquire about family history and risk factors for the development of breast cancer
 - To establish the etiology of the lesion as a cystic or solid
8. The performance of mammography in a woman with a breast mass
- Should be postponed until days 3-10 of the menstrual cycle
 - Is mainly used to exclude occult lesions in the non-involved breast tissue.
 - Is an effective means to rule out breast cancer in the palpable lesion
 - Must occur before any attempt is made to perform fine needle aspiration of the breast.
9. Which of the following is **TRUE** of breast masses?
- It is possible to distinguish cysts from solid masses by palpation.
 - A palpable breast mass in a 25-year old woman is most likely a cyst.
 - A palpable breast mass in a 40-year old woman is most likely a fibroadenoma.
 - A palpable breast mass in a postmenopausal woman should be considered carcinoma until proven otherwise.
10. The color of the fluid removed from a breast cyst
- Generally reflects the age of the cyst
 - Is lighter when the epithelial lining of the cyst degenerates
 - Is more often serous in older cysts
 - Should only appear yellow if the lesion is benign
11. A patient elicits nipple discharge which is reproducible during her clinical breast examination. The patient has never experienced spontaneous nipple discharge. Which of the following is appropriate:
- A Prolactin level
 - Culture and sensitivity testing of the discharge
 - Cytologic examination of the discharge
 - Reassurance

12. Which of the following is **TRUE** regarding spontaneous nipple discharge in a 35-year old non-lactating woman?
- If bilateral, greenish-brown, and from multiple ducts, the likelihood of cancer is high enough to warrant surgical intervention.
 - If single duct and bloody, the diagnosis is likely to be cancer
 - If unilateral and persistent, it is unlikely to resolve without surgical intervention.
 - If unilateral, persistent, and clear, carcinoma is unlikely.
13. Risks of screening mammography include all of the following except:
- Overdiagnosis of subclinical disease
 - Delays in diagnosis from false positive results
 - Discomfort associated with the performance of the procedure
 - Hypothetical radiation risk
14. The cost of screening mammography per year of life saved is about the same as that for which of the following interventions?
- Lung cancer screening
 - Cholesterol screening
 - Hormone replacement therapy
 - Seat belts/Airbags
15. The most common barrier cited by women for not having a screening mammogram is:
- The high cost of the screening is not covered by their insurance
 - Patients did not have any symptoms and didn't need the test
 - The marked discomfort that was experienced during a prior mammogram
 - The provider didn't inform the patient that a screening exam was needed
16. Aberrations of Normal Development and Involution (ANDI) have been classified into developmental stages. Benign breast disorders commonly occur during all of the developmental phases except:
- Postmenopausal phase (age 55 and above)
 - Early reproductive period (age 15 to 25)
 - Involutional phase (age 35-55)
 - Mature reproductive period (age 25-40)
17. Fibrocystic changes in the breast
- Can be clinically distinguished from cancer by the nodularity noted on physical examination
 - Occur most often in women aged 20 to 30
 - Generally are not found in women over the age of 50
 - Are easily distinguished from cancer on the basis of radiological examination

18. For women with an average life expectancy of 85, which of the following percentages most closely approximates their lifetime risk as calculated from birth for developing breast cancer? (Mark the best answer.)

- a. > 20%
- b. 16-20%
- c. 10-15%
- d. < 10%

19. Which statement about risk interpretation is correct?

- a. Absolute risk and relative risk are the same
- b. Multiplying two scores of relative risk can give an accurate appraisal of risk.
- c. Relative risk and absolute risk can change over time.
- d. Relative risk expresses the underlying probability of disease

20. How often do you recommend that women in the following age groups receive mammograms? (Mark one for each age category.)

> Women aged 40-49

- a. Never
- b. Annually
- c. Every 2 years
- d. Other (Please describe) _____

> Women aged 50-64

- a. Never
- b. Annually
- c. Every 2 years
- d. Other (Please describe) _____

> Women aged 65-79

- a. Never
- b. Annually
- c. Every 2 years
- d. Other (Please describe) _____

> Women aged 80+

- a. Never
- b. Annually
- c. Every 2 years
- d. Other (Please describe) _____

21. Indicate your level of agreement with each of the following statements. (Mark one box for each statement.)

> It is not important to spend much time on screening clinical breast exams because mammograms identify most early cancers

a) *Disagree Strongly* b) *Agree* c) *Agree Strongly*

> Performing regular screening clinical breast exams on my female patients is important to avoid malpractice claims

a) *Disagree Strongly* b) *Agree* c) *Agree Strongly*

- > The average woman aged 80 or older does not benefit from screening mammograms
 a) *Disagree Strongly* b) *Agree* c) *Agree Strongly*
- > In general, primary care physicians need more education about how to manage suspicious mammogram findings
 a) *Disagree Strongly* b) *Agree* c) *Agree Strongly*
- > I would usually not order a screening mammogram for a 70 year old woman with multiple medical problems
 a) *Disagree Strongly* b) *Agree* c) *Agree Strongly*
- > The risk of breast cancer as a result of radiation exposure from screening mammograms is a concern for me.....
 a) *Disagree Strongly* b) *Agree* c) *Agree Strongly*

22. A 60 year old woman who has been in your practice for several years comes in for the evaluation of a new acute problem (productive cough and fever). You diagnose bronchitis and prescribe an antibiotic. She has not had a mammogram for three years. How likely are you to recognize that she is overdue for a mammogram, and recommend one during this acute visit? (Mark the best answer.)

- a) *Very unlikely* b) *Somewhat unlikely* c) *Somewhat likely* d) *Very likely*

23. For each of the topics below indicate how well prepared you are to counsel your patients and answer their questions?

- > Individual risk of breast cancer
 a) *Not well prepared* b) *Somewhat prepared* c) *Well prepared*
- > The risks of getting a mammogram
 a) *Not well prepared* b) *Somewhat prepared* c) *Well prepared*
- > The benefits of getting a mammogram
 a) *Not well prepared* b) *Somewhat prepared* c) *Well prepared*
- > The patient's fears and concerns about breast cancer
 a) *Not well prepared* b) *Somewhat prepared* c) *Well prepared*
- > The effectiveness of mammograms
 a) *Not well prepared* b) *Somewhat prepared* c) *Well prepared*

24. Counseling patients to change negative behaviors is not helpful because they usually do not change. (Mark the best answer)

- a) *Strongly disagree* b) *Disagree* c) *Agree* d) *Strongly agree*

APPENDIX 11

GAIL Model Cases

Application of the Gail Model to the Risk Assessment for Breast Cancer

Case 1 – Ruby R

Patient Presentation and Questions

**Completed Patient Form on Risk Assessment and
Considerations and Contraindications to Tamoxifen Use**

Case # 1: Ruby R.:

Ruby R. is a 50 year old woman who has been a patient for 12 years. Her 42 year-old sister was recently diagnosed with a recurrence of breast cancer, manifested by liver metastasis. Ruby has been reading about the ability of Tamoxifen to reduce the risk of breast cancer in women who have a family history. She brings in a magazine advertisement that reads "breast cancer ... now there is something you can do." She states the following:

"I think about the fact that my sister is going to die from breast cancer constantly. I can't get it off my mind. I have heard about a pill that can prevent breast cancer. I want to take it to prevent this from ever happening to me."

Risk data and answers to questions about considerations for Tamoxifen therapy are attached.

QUESTIONS:

1. Using the Gail Model risk assessment tool to calculate risk, complete the following:

What is Ruby R's 5-year absolute risk for breast cancer? _____

What is Ruby R's lifetime absolute risk for breast cancer? _____

How do these numbers compare with a woman of her age and race with no risk factors (use ages 14 and 18 as age at menarche and age at 1st live birth, respectively).

5-year absolute risk of woman with no risk factors: _____

Lifetime absolute risk of woman with no risk factors: _____

2. Is Ruby R eligible for Tamoxifen therapy from a risk standpoint? _____
3. Are there any contraindications to Tamoxifen therapy in Ruby R? _____
4. How many women (per 1000) with the same risk profile as Ruby will be diagnosed with breast cancer during their lifetime? _____/1000
5. How many "average risk" women of Ruby's age and race will be diagnosed with breast cancer during their lifetime? _____/1000
6. The patient believes that Tamoxifen will prevent breast cancer in her case. Is this belief correct? How will you respond to her?
7. The patient has an understanding that Tamoxifen reduces mortality from breast cancer. How will you address this?

ANSWERS

CASE #1 – Ruby R.

1. Using the Gail Model risk assessment tool to calculate risk, complete the following:

What is Ruby R's 5-year absolute risk for breast cancer? 1.7%

What is Ruby R's lifetime absolute risk for breast cancer? 15.5%

How do these numbers compare with a woman of her age and race with no risk factors (use ages 14 and 18 as age at menarche and age at 1st live birth, respectively).

5-year absolute risk of woman with no risk factors: 0.6%

Lifetime absolute risk of woman with no risk factors: 6.0%

2. Is Ruby R eligible for Tamoxifen therapy from a risk standpoint? Yes
3. Are there any contraindications to Tamoxifen therapy in Ruby R? No
4. How many women (per 1000) with the same risk profile as Ruby will be diagnosed with breast cancer during their lifetime? 17 /1000
5. How many "average risk" women of Ruby's age and race will be diagnosed with breast cancer during their lifetime? 155 /1000
6. The patient believes that Tamoxifen will prevent breast cancer in her case. Is this belief correct? How will you respond to her?

This belief is not correct. I would explain to the patient that Tamoxifen has been shown to reduce the risk for breast cancer in about half of the patients who took the medication over a 5-year period.

I would also explain that it is not known yet for how long this risk reduction is sustained.

7. The patient has an understanding that Tamoxifen reduces mortality from breast cancer. How will you address this?

I would explain to Ruby that the study that is looking at the outcome of death reduction has not been long enough to draw any conclusions and that for that reason, it is premature to conclude that Tamoxifen can reduce the risk of death from breast cancer. It makes sense that if breast cancer itself is reduced, that death from it will be, but this has not been conclusively demonstrated yet.

Application of the Gail Model to the Risk Assessment for Breast Cancer

Case 2 – Maria G

Patient Presentation and Questions

**Completed Patient Form on Risk Assessment and
Considerations and Contraindications to Tamoxifen Use**

Maria G. is a 45-year-old Hispanic woman. Her mother died of breast cancer when Maria was 16. Her 42-year old sister was diagnosed with Stage II breast cancer 3 months ago. Maria is well except for a history of a pulmonary embolism on birth control pills a year ago. She has completed a full course of anticoagulant therapy and is currently on no medications. She states:

Risk data and answers to questions about considerations for Tamoxifen therapy are attached.

1. What race consideration will you use to calculate the risk for breast cancer in Maria G? What what you tell her in this regard?

- What is Maria G's 5-year absolute risk for breast cancer?**

What is Maria G's lifetime absolute risk for breast cancer?

How do these numbers compare with a woman of her age and race with no risk factors (use ages 14 and 18 as age at menarche and age at 1st live birth, respectively).

5-year absolute risk of woman with no risk factors:

Lifetime absolute risk of woman with no risk factors:

2. Is Maria G's risk high enough to be eligible for Tamoxifen therapy?
3. Are there any contraindications to Tamoxifen therapy in Maria G?
5. Maria G is interested in taking a 5-year course of Tamoxifen within the next few years. What is your advice to her about taking Tamoxifen?

6. How should Maria G be followed because of her high-risk status?

ANSWERS

CASE #2 – Maria G.

1. What race consideration will you use to calculate the risk for breast cancer in Maria G? What what you tell her in this regard?

I would use the "Caucasian" category because it will predict for the highest risk of the items used in the Gail model, if the patient was comfortable with this. I would explain to the patient that the risk assessment tool does not apply specifically to her race and the reason why I propose using the calculation based on the Caucasian category is because it will estimate the highest risk that the gail model calculates. I will explain also that it is likely that by doing this, we might be overestimating the risk as it applies to most Hispanic women. Because of her family history however, the risk is more accurate than it might otherwise be.

2. Using the Gail Model risk assessment tool, complete the following:

What is Maria G's 5-year absolute risk for breast cancer?

2.4%

What is Maria G's lifetime absolute risk for breast cancer?

25.8%

How do these numbers compare with a woman of her age and race with no risk factors (use ages 14 and 18 as age at menarche and age at 1st live birth, respectively).

5-year absolute risk of woman with no risk factors:

0.5%

Lifetime absolute risk of woman with no risk factors:

6.4%

3. Is Maria G's risk high enough to be eligible for Tamoxifen therapy?
4. Are there any contraindications to Tamoxifen therapy in Maria G?
5. Maria G is interested in taking a 5-year course of Tamoxifen within the next few years. What is your advice to her about taking Tamoxifen?

Yes

Yes

I would explain to the patient that the benefits of Tamoxifen are outweighed by the risks in her case because of her history of a blood clot to her lung. I would explain that Tamoxifen acts a lot like the birth control pills that she took that led to her last blood clot and that another one could be fatal. In her case, therefore, Tamoxifen is contraindicated.

6. How should Maria G be followed because of her high-risk status?

She should get mammography every year, and CBE twice a year, about 6 months apart. She should do monthly BSE and call the office if she has any questions at all.

Application of the Gail Model to the Risk Assessment for Breast Cancer

Case 3 – Janine J

Patient Presentation and Questions

**Completed Patient Form on Risk Assessment and
Considerations and Contraindications to Tamoxifen Use**

Case #3 – Janine J.

Janine J. is a 35-year old African-American woman who is a new patient to your practice. Her mother and sister were diagnosed with breast cancer 2 years apart from one another just last year. She is concerned but feels fatalistic about her ability to really do anything about it. Janine tells you:

"I'm very anxious to become pregnant this year. My husband and I have agreed we're ready for a child now. I figure, it's now or never, since I'm already 40 years old."

Risk data and answers to questions about considerations for Tamoxifen therapy are attached.

QUESTIONS:

1. Using the Gail Model risk assessment tool, complete the following:

What is Janine J's 5-year absolute risk for breast cancer? _____

What is Janine J's lifetime absolute risk for breast cancer? _____

2. Is Janine J's risk high enough to be considered for Tamoxifen therapy? _____
3. What is the best advice for Janine J about the timing of her possible pregnancy and her decision about the potential use of Tamoxifen?

The scene shifts to 5 years later. Janine J had a healthy baby girl at age 42. Two years later, it was necessary for her to have a total hysterectomy because of symptomatic uterine fibroids, and a bilateral salpingo-oophorectomy was done at the same time. She has been taking Premarin^R since then. Janine J. says, "My hot flashes were unbearable, and I couldn't sleep for weeks on end until the estrogen kicked in." Recently, she had a breast biopsy for a mammographic abnormality which revealed atypical epithelial hyperplasia.

You would like to re-assess her breast cancer risk. Risk data and answers to questions about considerations for Tamoxifen therapy are attached.

QUESTIONS:

4. Using the Gail Model risk assessment tool, recalculate Janine J's risk.

What is Janine J's 5-year absolute risk for breast cancer now? _____

What is Janine J's lifetime absolute risk for breast cancer now? _____

5. Janine has heard that Tamoxifen can cause endometrial cancer. How should she be advised?
6. Using 1-3 sentences, discuss the use of Tamoxifen in a woman on HRT.

ANSWERS

Case #3 – Janine J.

1. Using the Gail Model risk assessment tool, complete the following:

What is Janine J's 5-year absolute risk for breast cancer?

1.7%

What is Janine J's lifetime absolute risk for breast cancer?

19.9%

2. Is Janine J's risk high enough to be considered for Tamoxifen therapy?

Yes

3. What is the best advice for Janine J about the timing of her possible pregnancy and her decision about the potential use of Tamoxifen?

Janine should discontinue birth control pills and attempt to get pregnant as soon as possible. She will be eligible for Tamoxifen after her child-bearing is complete. She should take Tamoxifen for 5 consecutive years, without interruption, for effective breast cancer prevention.

4. Using the Gail Model risk assessment tool, recalculate Janine J's risk.

What is Janine J's 5-year absolute risk for breast cancer now?

5.1%

What is Janine J's lifetime absolute risk for breast cancer now?

33.9%

5. Janine has heard that Tamoxifen can cause endometrial cancer. How should she be advised?

While this is true, it would not affect her since she has had a hysterectomy.

6. Using 1-3 sentences, discuss the use of Tamoxifen in a woman on HRT.

Because the mechanism of action for Tamoxifen and estrogen replacement therapy are similar, the simultaneous use of both medications is discouraged. It is possible that the estrogen replacement therapy would counteract the Tamoxifen, and the effect of both drugs taken simultaneously is unknown. Given this patient's family history and recent history of atypical epithelial hyperplasia on breast biopsy, she should not stay on estrogen replacement therapy for long periods unless her hot flashes cannot be controlled. The first priority would be to take her off from ERT within the next 5 years, and then, if she can tolerate it, add Tamoxifen for the next five years.

APPENDIX 12

Evaluation Results from Workshops

YEAR ONE

Essentials of Breast Care for Primary Care Physicians Training Summary

St. Lawrence, Sparrow, Midland, Kalamazoo, Saginaw

31 Faculty + 84 Residents = 115 Total Evaluations

MSU Department of Family Practice; MSU Department of Surgery; Department of Defense
Program Evaluation and Attendance Record

Office of Continuing Medical Education, College of Human Medicine

This activity has been planned and implemented in accordance with the Essential Area and Policies of the Accreditation Council for Continuing Medical Education (ACGME) through the joint sponsorship of Michigan State University, College of Human Medicine and the US Department of Defense. Michigan State University, College of Human Medicine is accredited by the ACGME to provide continuing medical education for physicians and takes responsibility for the content, quality and scientific integrity of the CME activity.

Michigan State University, College of Human Medicine designates this educational activity for a maximum of 8 hours in category I credit towards the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

Key- Items 1-15 tabulations = Faculty(F) – Resident /Staff answers (R)

Please place one check for each evaluation item in the chart below.

Item for Evaluation	Poor		Satisfactory		Good		Excellent	
	F	R	F	R	F	R	F	R
1. Accuracy and timeliness of the content.			4	5	1	30	26	49
2. Relevance to your daily practice.					3	15	28	69
3. Impact on your professional effectiveness.			1	3	9	19	21	62
4. Relevance of content to learning objectives.			1	1	4	19	26	64
5. Objective of understanding breast cancer incidence and prevalence.					5	35	25	49
6. Objective of understanding the national guidelines for screening.		1		9	12	41	19	33
7. Objective of understanding risk factors for breast cancer.				4	9	33	22	47
8. Objectives of the rationale for breast cancer screening.			1	3	7	28	23	52
9. Objective of understanding steps to take in a workup of abnormal findings.				2	6	21	25	62
10. Objective of utilizing the GAIL model to predict individual patients' risk.	1		1	9	5	34	24	40
11. Objective of using proper technique in performing a CBE.			1	3	7	22	22	60
12. Objective of including all the steps to a complete breast health examination.			1	4	4	21	25	60
13. Objective of identifying breast lumps in silicone breast models.			1	6	9	34	21	44
14. Objective of utilizing a chart reminder/guideline system for screening and follow-up of breast abnormalities as part of practice.		1	5	17	10	33	16	33
15. Overall evaluation of this training.			1	2	3	20	26	62

(One Faculty did not rate #15)

OVER PLEASE

(General Comments (Highlighted sections are from faculty evaluations.)

1) HOW COULD THE ABOVE SEMINAR OBJECTIVES HAVE BEEN MET MORE EFFECTIVELY?

- Statistics/epidemiology
- Would have liked more discussion of screening guidelines.
- I am skeptical about the chart reminder system – we already have a dozen other pet project reminders and not all can be foremost in our minds.
- It was too long; I am brain dead. Clinical work interrupted by thought process (own patient crisis). Went thru algorithm at end quite *tired??*
- Shorten time period. Most information is basic and may be excluded. Possibly integrating(sic) hands on with lectures
- Charting not explicitly covered
- It was overall an excellent overview. I wouldn't change a thing. I especially appreciated the use of silicone models.
- State the objectives more clearly at the beginning of the day.
- A long day but worthwhile
- I think all of you did a fine job in presenting a lot of material in a short period of time. I have no suggestions.
- I know that a pre-post test methodology helps in your data analysis and research design, but even though I probably demonstrated an "increase" in knowledge I couldn't say I have learned enough to impact my practice. Perhaps a case-based approach based on evidence would help. Greater emphasis on algorithms and processing patients with problems as well as screening rationales.
- No change.
- Did a great job.
- Excellent course – ½ day seminar would be more beneficial.
- Run close to schedule – 1 hour break for lunch to re-charge.
- I would like to know more about how to use, and apply, the Gail system for *st?? tax??/assessment/screening*.
- Has finding different lumps in silicone breast models ever been equated with finding them on real women? I sort of doubt it – if not, then question the success of effectively teaching the silicone breast. Exam may not be worth the time.
- Feedback on silicone model testing station
- The day is very long but all material relevant. So somehow getting more time without having to do something during lunch.
- The seminar was too long. Need to decrease length or split into a 2-day session. Live models were excellent addition to learning.
- Very well done!
- As always: brevity is the soul of wit: although all information is good, try to pare down to essentials! Nine hours is a long time.
- No improvements. It was great.
- Less basic science.
- Well done as is.
- Less info.
- Give us 2 sessions, instead of 1 long session.
- Time crunch wouldn't have been a problem if everyone knew where to be @ 0745 (Sparrow's fault)

- Less time didactic. More time "hands on"
- 1) D??? chart reminder system. 2) Less palpation of silicone models – fatigue factor
- 1) It was great. 2) Laminate algorithm cards?
- No suggestions
- Well delivered. Can't think of anything right now.
- More breaks!
- No specific suggestions or comments; excellent seminar. Very applicable to daily practice. Manual provided with seminar excellent resource.
- I found this day to be extremely helpful.
- Help stratify risk assessment – more.
- Done quite well - I would like to have seen examples of chart reminder/tracking forms.
- Clarify the setting of the model breast exam, e.g., "take no history" or "Do only exam" was unclear what the goal was initially in the exam.
- Simply need to condense the didactic material to 2 hours maximum. You need to allow time for lunch breaks. Most of the first 2 hours could have been combined into 45 minutes or one hour. Too much time on simple material. Give examples of good (and maybe even bad) documentation. Algorithms should be skeleton of lectures not afterthought at end.
- The medico-legal arguments aren't compelling for me to the extent which they were presented.
- If possible to include FNA into course – possibly weekend – 2 days.
- The seminar was great
- Very well organized and presented. No specific suggestions
- It was very effective
- More specifics (anonymous) with actual cases that went to court, i.e., chronology of events
- Break up portions of PM section into AM
- Overall fantastic, maybe more frequent but shorter breaks would help keep audience sharp.
- More specific guidelines for different age groups and risk factors; more specifics on risk factor; more information and emphasis/example on effectiveness and side effects of Tamoxifen therapy.
- Excellent Conference
- More time could be allocated to explain "risk" calculations and perhaps fewer cases?? to complete in the 20 on post test. A bit more detail on tamoxifen therapy would be helpful. I'm not well versed in it yet.
- Speed up morning session, possibly examine different models.
- Good job. Just a very long day.
- Went very well, long day though.
- It was great.
- Everybody was good. Maybe less time on practice models; get to (the) testing right away after first run on models?
- Instant feedback on Gail Model Risk exercise.
- Teaching is most effective technique in teaching self exam.
- They were well presented and accomplished.

2) WHAT ARE YOUR SUGGESTIONS FOR IMPROVING THE ORGANIZATION OF THE COURSE?

- ½ day vs. whole day
- None
- As above (see 2nd bullet in Q1) integration of skills and lecture
- Do two ½ days
- Work at allowing a break sometime in the afternoon
- One day-long seminar does seem long – perhaps break it up into 2 half-day sessions.
- Silicone breast model was long and repetitious.
- Try and cut (to) 1 hour of lecture time. This will be hard because it is all important, there is just too much lecture in this day.
- Well organized. Lots of material for one day.
- Alternate lectures/workshops if possible.
- More time by 1 hour
- My only recommendation is to start/stay on time.
- See above: Excellent course – ½ day seminar would be more beneficial
- Same as above: Run close to schedule – 1 hour break for lunch to re-charge.
- Organized well.
- Nice job currently.
- Less silicone model practice. I'm not sure it helps real exams.
- Need to give guidelines for examining live models before we go in to the rooms.
- It was well organized.
- Excellent!
- Gail Calculators
- As above
- More room – more breaks – more hands-on
- Start promptly
- Spend less time on basics, i.e., anatomy; more time on subjects like use of Tamoxifen, Gail model
- Hands-on FNA on *oroze*!/?
- See above: Overall fantastic; maybe more frequent shorter breaks would keep audience sharp.
- See above: The day is very long but all material relevant. So somehow getting more time without having to do something during lunch
- Course is organized well, just decrease the time playing with rubber models.
- See above: As always: brevity is the soul of wit: although all information is good, try to pare down to essentials! Nine hours is a long time Consider deleting or curtailing use of silicone models.
- All very good.
- It was a bit long and tiring – could possibly be compacted into a shorter time period.
- None
- Be clear about meeting location.
- Probably do not need to repeat silicone breast exams.
- Less info
- Give us 2 sessions, instead of 1 long session.
- Not sure what the objective of the “documentation” section was. Possibly eliminate?
- Well organized.
- Well done.

- Very well organized. Appreciated you staying on time/on track
- If possible, break up practice/test sessions and lecture. Probably less efficient, but easier to stay awake, keep fingers from falling off.
- More breaks.
- None
- None
- Condense the didactics (breast exam teaching could also be condensed). Leave adequate time for lunch and answering phone calls at breaks. Add FNA training!! Add video of cyst aspiration beginning to end.
- Very good course
- Way too long in the afternoon – I would prefer just once with the real patient models p lecture with feedback.
- Very well organized and very practical.
- Break up the morning lectures into one hands on (like maybe the silicon models).
- None
- AV failure
- Did good with no changes.
- See above
- Well structured (& delivered!) Range of answers in pre & post test are a bit restrictive (strongly disagree – then agree) without much middle ground. It does force a commitment to answer. But, not necessarily the participants' "true" opinion.
- Make it little shorter

3) PLEASE IDENTIFY ADDITIONAL NEEDS/TOPICS FOR FUTURE EDUCATIONAL OFFERINGS.

- Additional lectures/workshops for FNA
- Breast aspiration/Biopsy workshop
- New drugs for prevention of breast cancer in high risk patients
- A "hands-on" workshop to take the place of 1 hour of lecture time
- Fine needle aspiration
- Assessment of local standards: 1) ob/gyn approach, 2) surgical approach, 3) local faculty vs. residency
- Fine needle aspiration
- Procedural workshops on injections.
- Use of natural progesterones.
- Fine needle aspiration
- None
- FNAB skills instruction
- Find most 1st year male residents can't do an adequate pelvic exam
- Would love a session on FNA aspiration of breast lesions
- Clarification of when to use tamoxifen therapy.
- FNA
- How to do FNA
- Not more effective but maybe quicker
- HTN, Smoking cessation, DM, Pap & cervical cancer.
- Other GYN screening/prevention issues; other women's health issues (i.e., how do we do screening women for cardiac disease.
- Performing FNA.
- More info needed re FNA
- Male testicular exam; pap & pelvic exams
- Fine needle aspiration training.
- Would be interested in future workshop on FNAB
- Procedure for FNA and FNAB
- More literature data worldwide
- FNA
- FNA techniques/equipment
- Patient counseling when abnormalities are found
- Brief word on surgical options
- The exact consistency or feel of a mass, i.e, how to tell if it is suspicious or not; (*B/c the triple felt states it mass look benign on all then the 99% benign?!?*, but how do we know when we are palpating if it was benign.
- Prostate care – similar format
- More specific info on Tamoxifen
- More specific information regarding management of Paget's disease, inflammatory carcinoma, lymph nodes biopsy.
- Procedure like FNB, Torcut ??, etc.
- None
- More discussion of cases involving using tamoxifen

- Give us calculators!
- None
- Good handouts. Will probably use the flow sheets
- More advance notice on agenda could be helpful in planning coverage
- Virtually everyone uses mammograms to rule out cancer. Perhaps more emphasis on this change of thinking would be helpful.
- Excellent course
- Very helpful
- Great Program
- Include checklist for CBE – something that might be included in the chart.
- Thanks. Please publish results and send me a copy!!
- Breaks q/o?? are helpful
- Lecture portion very good/informative
- Drs. Osuch and Zuber: excellent instructors and motivators
- Use of the patient/instructors was very helpful - gave great feedback.
- Thanks for coming. The teaching was great.
- This was a remarkable course.
- Silicone models too “stiff” – hurt fingers. Less greasy food.
- Lectures-excellent speakers! Nice job all the way around.
- Much appreciated. – Thank you!
- Thank you for coming and reemphasizing this very important aspect of primary care.
- Thanks for a great day.
- This was a much needed topic and I enjoyed the course.
- The course can be done yearly or every other year
- Emphasize that the order of CBE exam is not as important as completing all components. Overall excellent course – learned a great deal
- Excellent presentation!
- It was an excellent and wonderful course.
- It was an excellent course and I've learned a lot. Thank you. I hope you will do it next year with some changes.
- A disclosure statement is needed with pharmaceutical contributions or sponsorship and +?? conflict of interest of speakers.
- I do not feel it was necessary to do a breast exam on the same person 3 times. By the time I did the post test it just seemed so rehearsed. I would not spend so much time on FNB info.
- The cause is good but I'm concerned about the outcome of the study being flawed by the length of the program. Many people grew tired and irritable late in the day and the post-test information may not be as good if people quit trying. Maybe split it into two ½ day sessions.
- Feedback from patient before final encounter very effective, in aiding correction and instant feedback on Δ in style.
- Take-out food next time.

YEAR TWO

Essentials of Breast Care for Primary Care Physicians Training Summary

00-01 GENESYS, MUNSON, GRAND RAPIDS, McLAREN, & PROVIDENCE

32 Faculty, 87 Residents, 4 Nurses = 123 Total Evaluations

MSU Department of Family Practice; MSU Department of Surgery; Department of Defense

Program Evaluation and Attendance Record

Office of Continuing Medical Education, College of Human Medicine

This activity has been planned and implemented in accordance with the Essential Area and Policies of the Accreditation Council for Continuing Medical Education (ACGME) through the joint sponsorship of Michigan State University, College of Human Medicine and the US Department of Defense. Michigan State University, College of Human Medicine is accredited by the ACGME to provide continuing medical education for physicians and takes responsibility for the content, quality and scientific integrity of the CME activity.

Michigan State University, College of Human Medicine designates this educational activity for a maximum of 8 hours in category I credit towards the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

Key- Faculty (F) – Resident (R)

Item for Evaluation	Poor		Satisfactor		Good		Excellent	
	F	R	F	R	F	R	F	R
1. Accuracy and timeliness of the content.			1	3	6	36	25	52
2. Relevance to your daily practice.			1	1	6	16	25	74
3. Impact on your professional effectiveness.			2	2	10	23	20	66
4. Relevance of content to learning objectives. -1 Providence.			1	1	5	28	26	61
5. Objective of understanding breast cancer incidence and prevalence.			2	1	5	31	25	59
6. Objective of understanding the national guidelines for screening.		1	3	8	6	36	23	46
7. Objective of understanding risk factors for breast cancer.			1	1	6	36	25	54
8. Objectives of the rationale for breast cancer screening.			2	3	8	33	22	55
9. Objective of understanding steps to take in a work-up of abnormal findings.			1	2	4	34	27	55
10. Objective of utilizing the GAIL model to predict individual patients' risk -1 Providence	1		3	7	13	34	15	49
11. Objective of using proper technique in performing a CBE.			2	-	4	24	26	66
12. Objective of including all the steps to a complete breast health examination.			2	-	5	25	25	66
13. Objective of identifying breast lumps in silicone breast models.			5	7	11	36	16	48
14. Objective of utilizing chart reminder-guideline system for screening and f-u. -2 Munson	1	1	7	7	6	39	18	42
15. Overall evaluation of this training. -2 Genesys; -1 Providence; -1 McLaren			1	-	6	25	24	63

GENERAL COMMENTS (Highlighted sections are faculty feedback)

1) HOW COULD THE ABOVE SEMINAR OBJECTIVES HAVE BEEN MET MORE EFFECTIVELY?

GENESYS

- **Breast models could be improved.**
- **Well done; more comfortable lecture hall**
- **More time (2 ½ days); lot of material**
- Immediate feedback
- Ask everyone to put pagers on vibrate
- Spend more time on Tamoxifen
- Pre/post test not time-effective or necessarily needed in improving my skills. I understand it's needed for your data.
- Breast examination of the models a second time was redundant and the information shared could have been elicited after the first encounter. Efficient? It was not!
- I don't think so.
- Point more on the conclusions – especially regarding the algorithms used.
- Would not change as it was presented very effectively.
- For me excellent. I have never had such a good seminar before.

MUNSON

- **A few more breaks in AM; hard to sit still so long.**
- **Combine some epidemiology into one section vs. 2 or 3**
- Great
- Actually it moved well, not much down time. Excellent!
- Perhaps a little lighter on the epidemiological data, etc. It got a little overwhelming
- This course very effectively met the objectives. No changes necessary.
- More frequent breaks (just a couple).
- The objectives were met effectively.
- A lot of information packed into the day. Great combo of activities. Enjoyed feedback.
- Met objectives well
- A lot of info in one day—all excellent and well done.

GRAND RAPIDS

- **Excellent program**
- They were appropriate
- Excellent presentation
- All were met very effectively
- Very appropriate presentation of objectives
- May be able to be condensed (somewhat). Pace was a little slow overall
- Shorter, more frequent breaks
- Great
- None
- None

McLAREN

- Less time on didactic. More time on practical exercises.
- The lecture time needs to be revamped, e.g. include more breaks, etc.
- Didactic was too large. Some topics (ex. Tamoxifen use) is not something that I would give my patients and would defer to a specialist.
- Use a bigger room for presentation.
- Better understanding on how to translate the stations to patients.
- In a matter of a few days, not one!
- More practical clinical exam times.
- Objectives were clearly defined.
- Have first year residents do it before beginning of residency.

PROVIDENCE

- Very well done
- The seminar comes across as an information "blitz."
- Excellent presentations and handouts to go along - not further recommendations
- Make the lecture session more interactive
- Excellent
- Excellent
- No change
- No recommendation
- Some parts were redundant, need to shorten the day
- Better following time constraints
- Nothing
- It was done well so I don't know how you could be more effective
- Excellent presentation. Silicone models difficult to use but live models were great! Thanks.
- Too long
- More time for BCT [*breast care technique?*]
- Done very well

2) WHAT ARE YOUR SUGGESTIONS FOR IMPROVING THE ORGANIZATION OF THE COURSE?

GENESYS

- **A little less testing of silicone model (fingers hurt now).**
- Tips on examination of women with breast implants. Ask all participants to put pagers on "silent." Constant beeping was disruptive.
- One or two more live models might have made the transitions among the group go more quickly. Condense the lecture material (for less time in lecture) the course materials are well put together and easily read on one's own.
- Maybe break it into a 2-day ½ seminar? Overall was excellent program.
- I wish we had time to recheck ourselves on models before final trial.
- Reduce the introduction time and delve into content issues
- None
- No talking or instructions during pretest – distracting.
- Schedule is a little bit tight.
- Increase the number of live patient models.

MUNSON

- **Extremely well organized**
- **Very well organized**
- **Better explanation of format for actual patient exams prior to pretext exams.**
- None
- None. Continue
- None – very good
- Very well organized. Thank you.
- Very condensed. I felt rushed a little. Lectures were long.
- Much of the material was redundant. Less repetition could shorten the course.
- Overall excellent course
- It was well organized. Some feedback on the silicone breast models would have been helpful.
- Shorter, please
- Doing the silicone models twice seemed a little redundant.
- Very well organized
- Live models were a bonus; silicone models were difficult to palpate; feedback was helpful

GRAND RAPIDS

- Very well organized
- Well done
- None
- None. Well organized
- Five minute breaks between each individual lecture
- Probably not necessary to perform breast exam and utilize silicone models twice.
- Shorter lectures in the morning
- Alternative speakers 2 hours
- None
- Additional break during morning program; question need for repeat model exam after first try, presentation video on proper technique.

McLAREN

- **Lecture during the noon hour. Eliminate the computer part.**
- **Less didactic and more clinical.**
- **Need to eliminate CBE twice: lecture and video. Shorten the course more.**
- **None.**
- **Make it 2-day course.**
- **Speed up the pace of the lectures, it was too slow. Place only one breast per page of paper at the stations so we don't have to wait.**
- **Stick to time constraints/schedule.**
- **Use bigger room as well as few days, instead of one.**
- **More practical clinical exam times.**
- **Well organized course.**
- **None**

PROVIDENCE

- **Done very well**
- **Try to break up the didactic sessions a little more with activities/practice.**
- **I would focus on practical patient examples more**
- **None**
- **None**
- **None**
- **Less practice with silicon breast models – more with patient educators**
- **shorten the GAIL presentation – make it during lunch**
- **None, great job!**
- **The silicon models were difficult to feel**
- **A little long**
- **It was well organized**
- **Less (sic) lectures – if possible**
- **Table of contents**
- **Follow up with tracking of patients – timely manner**

3) PLEASE IDENTIFY ADDITIONAL NEEDS/TOPICS FOR FUTURE EDUCATIONAL OFFERINGS.

GENESYS

- **Male breast care**
- **Male exams for testicular abnormalities**
- Devote more time to Tamoxifen.
- I have background in extensive statistics analysis. Many of my counterparts were not clear on relative vs. absolute risks. It's elementary, but I think a bit more time dedicated to this and less on historical aspects of the study would go far.
- None
- Male genitalia exam
- 2-day course including Rx and after Rx.

MUNSON

- **Breast cyst aspiration/FNA techniques for resident/faculty**
- None
- None
- None
- Cases were great.
- Colon cancer screening; pap/cervical cancer

GRAND RAPIDS

- Topics well covered
- Overall very thorough
- None
- Diabetes
- Techniques – breast. FNA Osprial(?), Rx
- Role of evaluation exams in patients at risk for breast cancer.

McLAREN

- **More care oriented would've been helpful.**
- **Maybe treatments for breast cancer.**
- GYN exam and management of abnormal findings.
- It would be nice to practice FNA, simulate cysts in breasts and have us aspirate.
- None.

PROVIDENCE

- **More ideas on reminders for screening; to catch patients not coming in for health maintenance exams.**
- **Further discussion of risk of HRT/DRT, benefits commonly encountered pt. questions.**
- Common skin lesions and tx.
- Pelvic exam
- Should have a FNA workshop
- Live women with breast findings
- None
- Very beneficial as is
- Screening guidelines
- Colon cancer; ulcerative colitis

4) PLEASE LIST ANY QUESTIONS YOU HAVE REGARDING THIS STUDY.

GENESYS

- Excellent study. I wish I had it as a med student.
- Breast models not very lifelike...
- None

MUNSON

- Breast cyst aspiration/FNA techniques for resident/faculty
- None
- None
- Cases were great.
- Colon cancer screening; pap/cervical cancer

GRAND RAPIDS

- Can't think of any at the moment, however, the binder [manual] is great for experience.

McLAREN

- How were the participants selected? Any exclusion criteria?
- Update information on HRT/Tamoxifen.

PROVIDENCE

- Will we be able to see the results?
- None
- Very excellent presentation

5) OTHER GENESYS

MUNSON

- Well done. Thanks
- A bit too long, though I don't know what could have been omitted.
- Thanks. TM
- Great workshop!
- Great course
- Great!!!
- Great job.
- Thank you. I feel much more comfortable in my breast exam skills now.
- It was just a very long day with a lot of information. Would be helpful to have refresher courses periodically.
- Well done! Felt pretty comfortable prior to course; now I am confident.
- Taking the pretest right before the lectures I think biased me to listen for the answers and remember them after the presentation.

GRAND RAPIDS

- Well done. Some discussion of effective CBE
- Overall excellent! Statistics, evidence, practical, all ver relevant.
- Please thank patient models. It was appreciated greatly.
- Excellent course. No specific recommendations regarding the organization or presentation of the materials.
- Excellent
- Great workshop – very informative, practical with feedback, awareness of importance of better breast exams
- Thanks
- Well organized – great information! Thank you
- Excellent course
- Learned a lot; very helpful at this stage of our training.
- Felt workshop was an excellent review; lectures were brief and to the point, direct, but need more breaks! Slides were good and handouts had explanation for each slide. Silicone breast models need to be softer

McLAREN

- I was called away frequently for in-hospital patient care, so global evaluations on my part are significantly impaired. Thank you for the clear and comprehensive written material. I regret that I didn't get good exposure to the Gail materials.
- I still feel ill prepared to talk to my patients regarding their risks of breast cancer and addressing their fears. How do you translate ratios and numbers to layman's terms? Would have liked a doctor present in the room when examining real model patients.

PROVIDENCE

- **Excellent, practical course that all residents/physicians should have the opportunity to attend.**
- **Very well done**
- **Excellent program! I learned a lot in terms of performing an effective CBE, which will serve me well for the rest of my clinical training.**
- **The conference was very educational. I really liked having the patient educators so that technique could be evaluated not only by looking but also if pressing hard enough or too much. The silicone models were great for more practice in feeling different types of lumps.**
- **Very helpful. Especially the clinical skills. Lectures were also very helpful – good picture examples.**
- **Pre & post test on silicone models; may be less improvement noted since the models had to have 2-3x normal pressure, and examiners fatigue certainly influenced the post exams**
- **Excellent – very applicable.**
- **Good job**
- **Great job. I learned a lot, especially how better to do the CBE.**

Compiled & tabulated the composite results of 5 control agencies February 2001 – M.R. Struck

APPENDIX 13

Silicone Breast Model Coding Form

Essentials of Breast Care

A 5

July 15, 1999

Clinical Breast Examination Form

Pre-test Silicone Breast Models

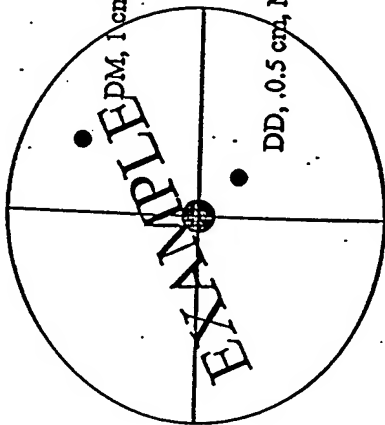
1 cm, H

These breasts simulate the breast tissue of a 50 year old woman.

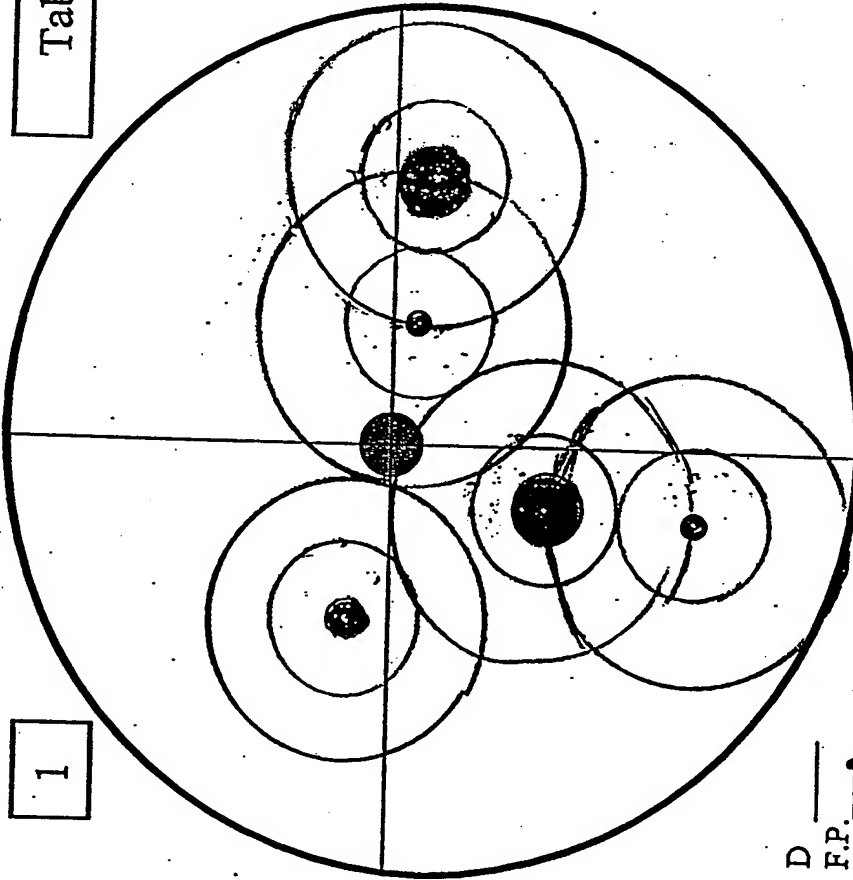
INSTRUCTIONS: Draw each lump in the appropriate location and indicate in the following order:

1. Depth: Medium (DM), Deep (DD)
2. Size: 0.3 cm, 0.5 cm, 1.0 cm
3. Hardness: Hard (H), Medium (M), Soft (S)

Table 1

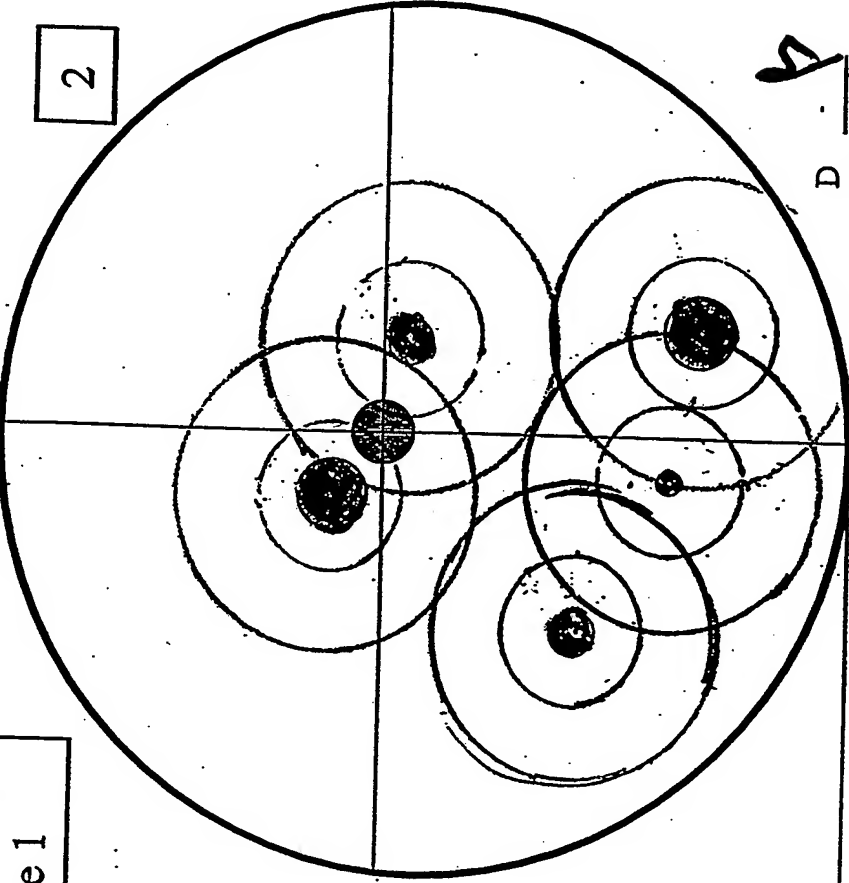


1



D
F.P. A

2



D

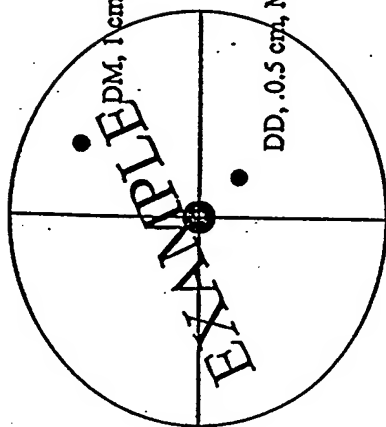
F.P. B

Total D _____ Total F.P. _____ Sensitivity _____ % Specificity _____ %

Essentials of Breast Care

Clinical Breast Examination Form

July 15, 1999



Post-test Silicone Breast Models

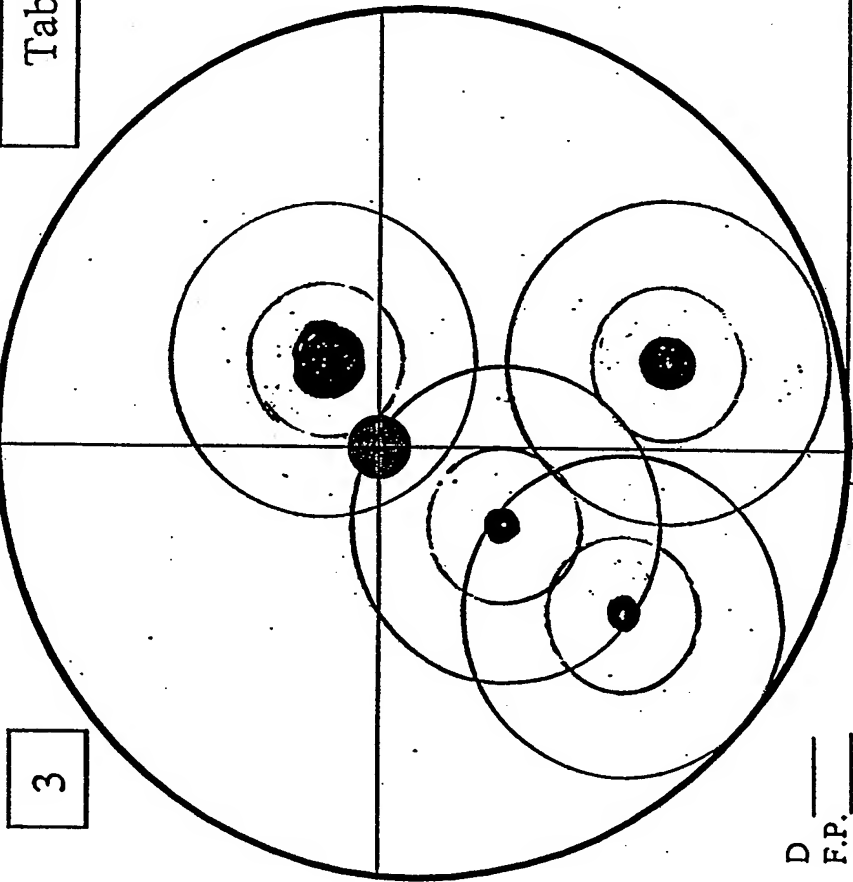
These breasts simulate the breast tissue of a 50 year old woman.

INSTRUCTIONS: Draw each lump in the appropriate location and indicate in the following order:

1. Depth: Medium (DM), Deep (DD)
2. Size: 0.3 cm, 0.5 cm, 1.0 cm
3. Hardness: Hard (H), Medium (M), Soft (S)

3

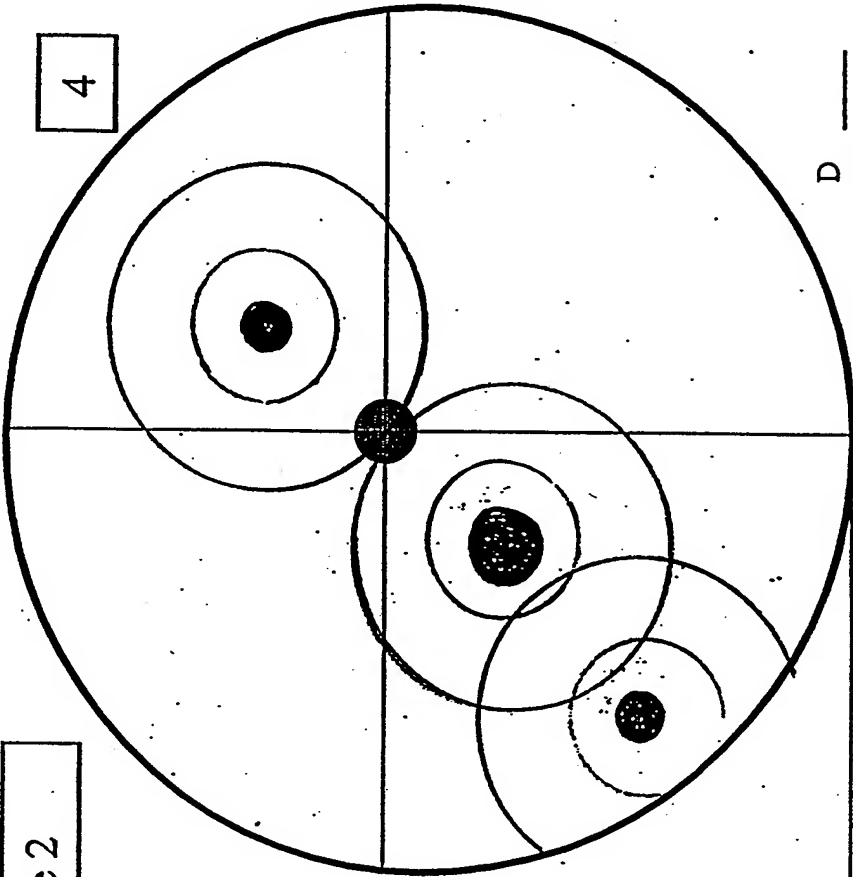
Table 2



D
F.P.

C

4



D
F.P.

D

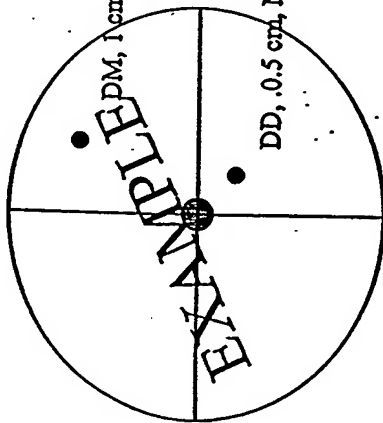
Total D ____ Total F.P. ____ Sensitivity ____ % Specificity ____ %

Essentials of Breast Care

Clinical Breast Examination Form

Pre-test Silicone Breast Models

July 15, 1999



These breasts simulate the breast tissue of a 50 year old woman.

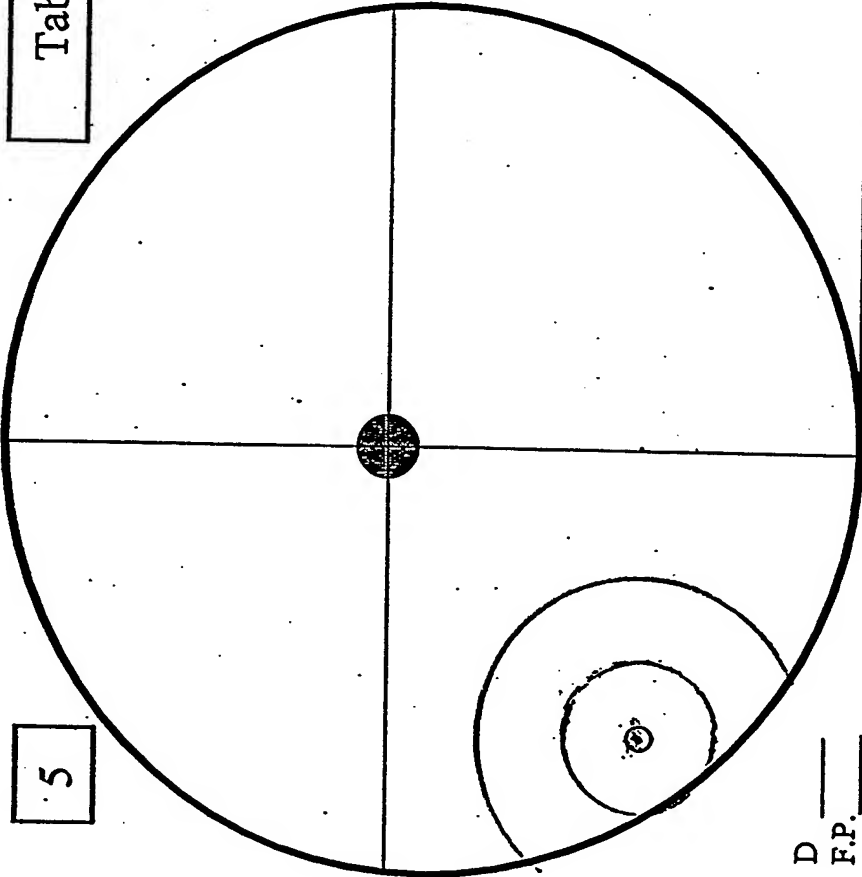
INSTRUCTIONS: Draw each lump in the appropriate location and indicate in the following order:

1. Depth: Medium (DM), Deep (DD)
2. Size: 0.3 cm, 0.5 cm, 1.0 cm
3. Hardness: Hard (H), Medium (M), Soft (S)

5

Table 3

6



D
F.P.

Total D _____ Total F.P. _____ Sensitivity _____ % Specificity _____ %

F_{none}
D
F.P.

E (1)

APPENDIX 14

Patient Instructor Coding Form

ESSENTIALS of BREAST CARE

Practice Session

Areola

Upper Outer Quadrant (UOQ)

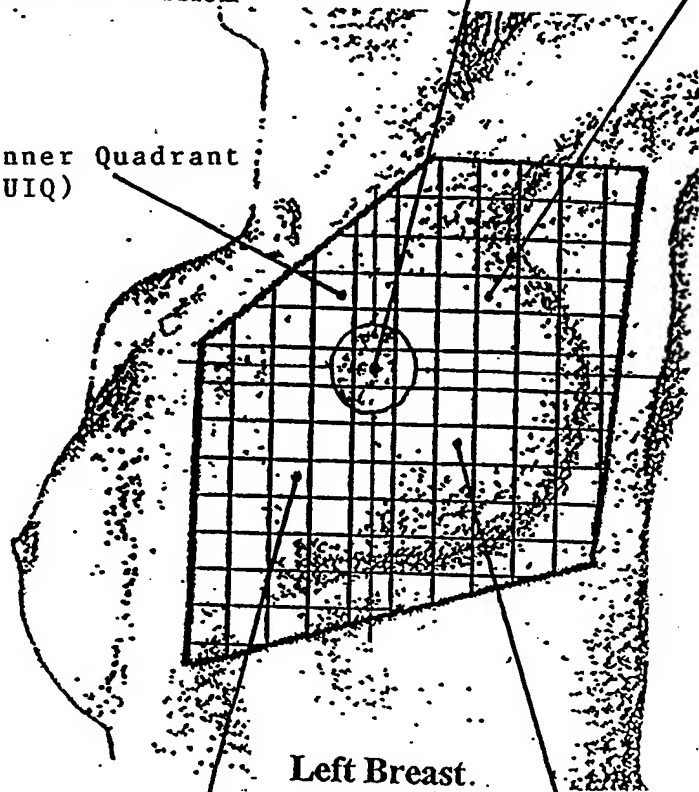
Upper Inner Quadrant (UIQ)

REGIONS OF THE BREAST
AFTER SEGMENTATION

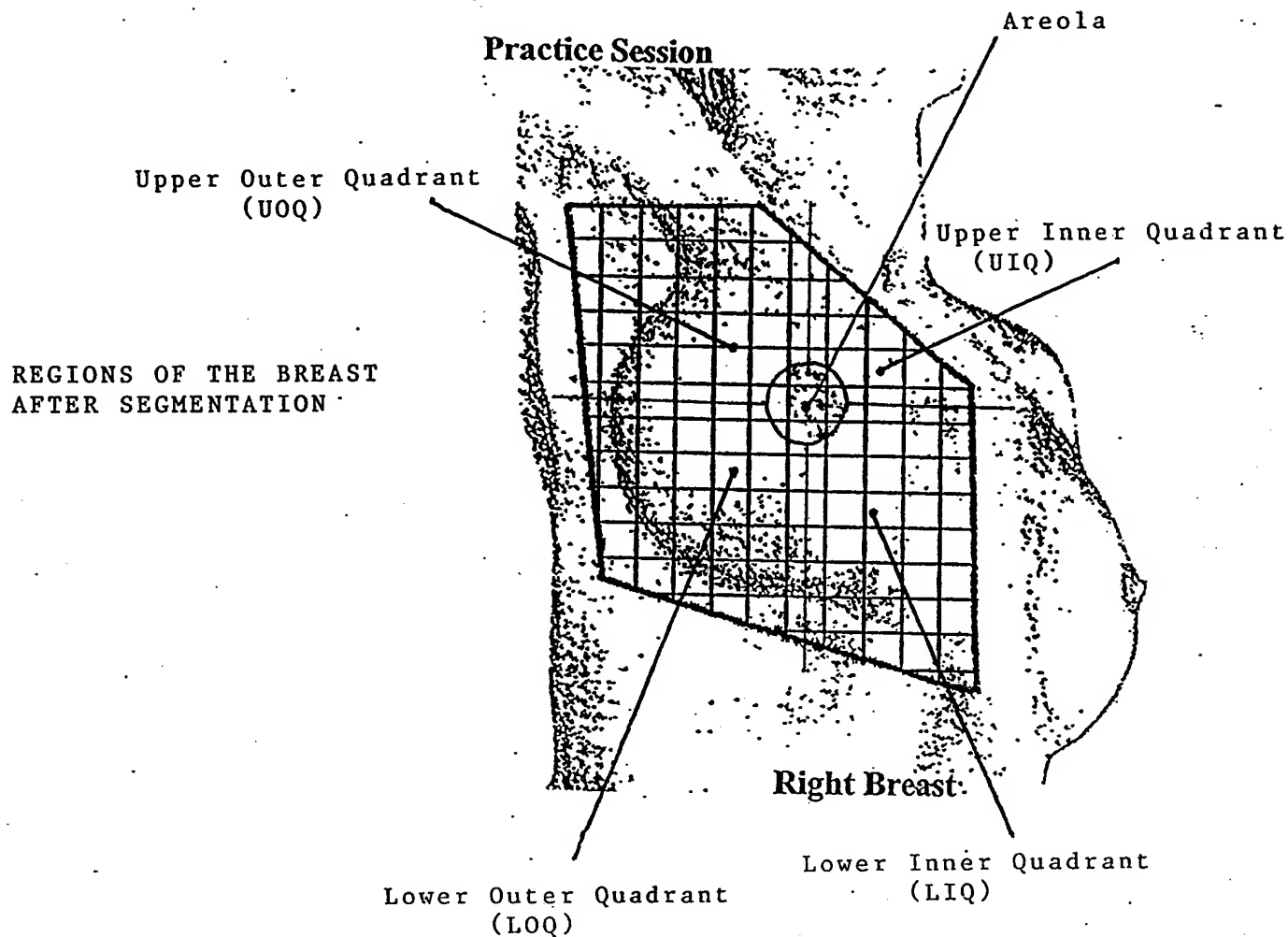
Left Breast.

Lower Outer Quadrant (LOQ)

Lower Inner Quadrant (LIQ)



ESSENTIALS of BREAST CARE



APPENDIX 15

Knowledge, Attitude and Behavior Scale Pre-Post Results Years One and Two

Physician Survey (Knowledge) - ALL IN %

Question 1

Site	Correct Pre	Correct Post	Correct InBoth	Improvement	Wrong Post
1	34	71	31	61	29
2	65	78	61	50	22
3	48	67	38	55	33
4	50	83	50	67	17
5	55	95	55	90	5
6	72	94	72	80	6
7	56	84	56	64	16
8	48	89	48	79	11
9	75	88	63	100	13
10	62	90	59	82	10
TOTAL:	55	83	52	70	17

Question 2

Site	Correct Pre	Correct Post	Correct InBoth	Improvement	Wrong Post
1	63	94	60	92	6
2	78	100	78	100	0
3	81	100	81	100	0
4	63	92	63	78	8
5	59	100	59	100	0
6	68	100	68	100	0
7	80	100	80	100	0
8	56	100	56	100	0
9	50	94	50	88	6
10	83	97	79	100	3
TOTAL:	68	98	68	95	2

Question 3

Site	Correct Pre	Correct Post	Correct InBoth	Improvement	Wrong Post
1	71	97	71	90	3
2	91	100	91	100	0
3	57	95	57	89	5
4	83	92	75	100	8
5	91	95	86	100	5
6	84	100	84	100	0
7	84	96	80	100	4
8	78	96	74	100	4
9	69	94	69	80	6
10	100	100	100		0
TOTAL:	81	97	79	93	3

Question 4

Site	Correct Pre	Correct Post	Correct InBoth	Improvement	Wrong Post
1	20	46	17	36	54
2	39	70	30	64	30
3	29	81	19	87	19
4	13	54	8	52	46
5	64	82	55	75	18
6	53	84	47	78	16
7	68	60	44	50	40
8	26	67	19	65	33
9	31	69	19	73	31
10	24	55	21	45	45
TOTAL:	35	65	27	58	35

Question 5

Site	Correct Pre	Correct Post	Correct InBoth	Improvement	Wrong Post
1	14	46	6	47	54
2	43	65	35	54	35
3	10	52	5	53	48
4	25	42	4	50	58
5	14	55	9	53	45
6	16	37	11	31	63
7	36	48	24	38	52
8	26	44	19	35	56
9	38	56	25	50	44
10	31	55	14	60	45
TOTAL:	25	50	15	47	50

Question 6

Site	Correct Pre	Correct Post	Correct InBoth	Improvement	Wrong Post
1	60	60	43	43	40
2	83	91	78	75	9
3	52	71	43	60	29
4	58	71	50	50	29
5	50	82	45	73	18
6	37	37	26	17	63
7	68	88	68	63	12
8	35	62	27	53	38
9	44	56	38	33	44
10	72	83	69	50	17
TOTAL:	57	71	50	50	29

Question 7

Site	Correct Pre	Correct Post	Correct InBoth	Improvement	Wrong Post
1	29	31	20	16	69
2	43	74	43	54	26
3	24	33	24	13	67
4	25	42	21	28	58
5	36	68	32	57	32
6	42	47	26	36	53
7	52	100	52	100	0
8	35	65	35	47	35
9	50	75	44	63	25
10	43	46	32	25	54
TOTAL:	37	57	32	39	43

Question 8

Site	Correct Pre	Correct Post	Correct InBoth	Improvement	Wrong Post
1	51	63	40	47	37
2	57	70	43	60	30
3	48	57	33	45	43
4	21	50	17	42	50
5	68	68	55	43	32
6	58	95	53	100	5
7	46	92	46	85	8
8	50	77	46	62	23
9	50	69	38	63	31
10	45	86	41	81	14
TOTAL:	49	72	41	61	28

Question 9

Site	Correct Pre	Correct Post	Correct InBoth	Improvement	Wrong Post
1	86	97	86	80	3
2	74	96	74	83	4
3	86	100	86	100	0
4	83	83	75	50	17
5	86	95	82	100	5
6	84	95	84	67	5
7	80	100	80	100	0
8	96	100	96	100	0
9	81	81	75	33	19
10	86	97	83	100	3
TOTAL:	85	95	83	81	5

Question 10

Site	Correct Pre	Correct Post	Correct InBoth	Improvement	Wrong Post
1	40	89	37	86	11
2	52	96	48	100	4
3	38	81	38	69	19
4	38	83	38	73	17
5	59	82	55	67	18
6	44	61	33	50	39
7	48	100	48	100	0
8	40	92	40	87	8
9	44	81	31	89	19
10	45	72	45	50	28
TOTAL:	45	84	42	77	16

Question 11

Site	Correct Pre	Correct Post	Correct InBoth	Improvement	Wrong Post
1	14	60	11	57	40
2	9	74	9	71	26
3	24	90	24	88	10
4	4	58	4	57	42
5	9	45	9	40	55
6	0	100	0	100	0
7	16	88	16	86	12
8	12	77	12	74	23
9	6	81	6	80	19
10	21	66	17	61	34
TOTAL:	12	73	11	70	28

Question 12

Site	Correct Pre	Correct Post	Correct InBoth	Improvement	Wrong Post
1	3	43	3	41	57
2	0	78	0	78	22
3	10	62	5	63	38
4	17	38	8	35	63
5	5	32	0	33	68
6	16	53	11	50	47
7	20	76	16	75	24
8	19	63	15	59	37
9	19	50	13	46	50
10	7	38	3	37	62
TOTAL:	11	53	7	51	47

Question 13

Site	Correct Pre	Correct Post	Correct InBoth	Improvement	Wrong Post
1	63	83	51	85	17
2	83	83	70	75	17
3	81	86	81	25	14
4	67	92	67	75	8
5	68	82	59	71	18
6	68	58	53	17	42
7	80	80	64	80	20
8	73	69	54	57	31
9	56	56	50	14	44
10	59	83	59	58	17
TOTAL:	70	78	60	59	22

Question 14

Site	Correct Pre	Correct Post	Correct InBoth	Improvement	Wrong Post
1	43	66	31	60	34
2	52	96	52	91	4
3	57	71	48	56	29
4	33	67	17	75	33
5	64	86	59	75	14
6	37	95	37	92	5
7	40	96	36	100	4
8	30	81	26	79	19
9	40	93	33	100	7
10	62	93	59	91	7
TOTAL:	46	83	40	81	17

Question 15

Site	Correct Pre	Correct Post	Correct InBoth	Improvement	Wrong Post
1	46	94	46	89	6
2	61	96	57	100	4
3	62	95	62	88	5
4	71	100	71	100	0
5	73	95	68	100	5
6	79	95	79	75	5
7	76	100	76	100	0
8	52	89	44	92	11
9	67	100	67	100	0
10	66	97	66	90	3
TOTAL:	64	96	62	93	4

Question 16

Site	Correct Pre	Correct Post	Correct InBoth	Improvement	Wrong Post
1	66	89	60	83	11
2	91	100	91	100	0
3	86	86	71	100	14
4	71	96	71	86	4
5	86	95	86	67	5
6	84	100	84	100	0
7	88	100	88	100	0
8	93	96	89	100	4
9	81	81	63	100	19
10	76	97	72	100	3
TOTAL:	81	94	77	91	6

Question 17

Site	Correct Pre	Correct Post	Correct InBoth	Improvement	Wrong Post
1	29	57	20	52	43
2	17	65	17	58	35
3	19	62	14	59	38
4	0	79	0	79	21
5	23	50	9	53	50
6	21	53	11	53	47
7	48	76	36	77	24
8	15	74	11	74	26
9	19	50	6	54	50
10	41	69	38	53	31
TOTAL:	24	64	17	62	36

Question 18

Site	Correct Pre	Correct Post	Correct InBoth	Improvement	Wrong Post
1	49	69	43	50	31
2	61	91	52	100	9
3	43	62	38	42	38
4	50	75	46	58	25
5	41	68	36	54	32
6	53	68	42	56	32
7	68	84	60	75	16
8	67	74	48	78	26
9	75	88	63	100	13
10	72	72	55	63	28
TOTAL:	58	75	48	63	25

Question 19

Site	Correct Pre	Correct Post	Correct InBoth	Improvement	Wrong Post
1	60	80	54	64	20
2	74	96	70	100	4
3	48	86	43	82	14
4	63	83	58	67	17
5	50	91	50	82	9
6	78	94	72	100	6
7	64	92	64	78	8
8	65	91	65	75	9
9	47	80	40	75	20
10	69	86	66	67	14
TOTAL:	62	88	59	76	12

APPENDIX 16

Patient Instructor Pre-Post Results Years One and Two

TEACHING LIVE MODEL BREAST EXAMINE TECHNIQUE PRE VERSUS POST

Site Number	% of the breast area examined			
	Pre	Post	Retention	p-value
1	83.6	99.7	14.2	<0.0001*
2	84.1	96.8	13.2	<0.0001*
5	88.2	91.0	2.8	0.1689
6	87.9	99.6	11.9	<0.0001*
7	86.1	99.2	13	<0.0001*
8	89.7	99.3	9.5	<0.0001*
9	88.5	95.8	7.9	<0.0001*
10	83.3	98.8	9.2	<0.0001*

All 8 Sites	87.2	97.7	10.4	<0.0001*
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*statistically significant with p-value less than .01

Score on Palpation (out of 5)					% who score a 5 out of 5	
Pre	Post	Retention	p-value		Pre	Post
3.3	4.3	1.1	<0.0001*		31.5%	64.7%
2.6	4.5	1.9	<0.0001*		18.0%	58.3%
3.5	4.0	0.5	0.0318		36.90%	60.50%
3.3	4.7	1.4	<0.0001*		45.0%	84.2%
2.9	3.7	0.9	0.0002*		26.9%	55.8%
3.4	4.6	1.2	<0.0001*		28.7%	83.9%
3.7	4.6	0.8	0.0017*		50.0%	79.4%
3.5	4.5	1.0	<0.0001*		37.1%	59.2%

3.3	4.3	1.1	<0.0001*	32.9%	68.5%
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APPENDIX 17

Silicone Breast Model Pre-Post Results Years One and Two

SILICONE BREAST MODEL SENSITIVITY AND SPECIFICITY

PRE TRAINING TESTING RESULTS VERSUS POST TRAINING TESTING RESULTS

Site Number	Sensitivity(%)			
	Pre	Post	Improve	p-value
1	53.6	69.8	17.8	<0.0001
2	72.1	73.2	-0.1	0.9678
4	58.6	69.7	11	0.0031
5	59.4	70.2	9.5	0.0115
6	60.6	61.9	2.4	0.6476
7	70.4	69.8	-0.6	0.8679
8	53.9	54.7	0.75	0.872
9	45.3	59.9	14.6	0.0003
10	62.3	63.8	0.75	0.7922
All 9 Sites	59.8	65.8	6	<0.0001

	Specificity(%)			
	Pre	Post	Improve	p-value
	48	59.5	9.6	0.1337
	48.1	41.7	-6.7	0.2193
	55.6	52.2	-2.5	0.677
	43	47.7	5.4	0.5588
	26.3	23.4	-2.5	0.7286
	15.4	43.9	28.6	<0.0005
	26.3	31	4.6	0.3117
	25.1	28.7	3.6	0.5779
	20	25.7	5.5	0.297
	35.1	39.5	5.5	0.011

BOLD FACE P-VALUES are statistically significant at cut-off less than .05

APPENDIX 18

Kappa Tests for Quality Assurance Years One and Two

YEAR ONE

Table 1: Kappa Results From Form-I (General Information Form)

Abstractor ID	Eligibility Code	Date Most Recent Office Visit (Q2)	Total Number of Visits Within 15 Months (Q3)	Total Breast Care Related Encounter(s)
11	*	*	77%	88%
12	*	*	86%	*
21	64%	*	72%	58%
22	69%	*	89%	64%
31	*	*	84%	88%
32	*	*	85%	74%
41	60%	*	74%	70%
42	84%	86%	*	*
51	*	*	*	*
52	85%	*	70%	*
61	84%	*	88%	59%
62	*	89%	*	87%
71	83%	*	*	75%
81	*	86%	74%	*
82	*	*	*	84%
91	*	*	*	77%
92	86%	*	86%	67%

Note: “*” = 100% Kappa Result

Table 2: Kappa Results From Form-II (Visit Entry Form)

Abstractor ID	Type of Contact (Q6)	Symptom Lump R (Q9)	Symptom Lump L (Q9)	CBE Documentation			Abnormal Lump R (Q11)	Abnormal Lump L (Q11)
				Inspection (Q11)	Palpation (Q11)	Lymph Node Exam (Q11)		
11	*	*	*	*	*	78%	*	*
12	*	*	*	*	*	67%	0 (83)%	0 (83)%
21	*	*	*	*	*	*	*	*
22	*	*	*	62%	*	*	*	*
31	*	*	*	*	*	*	*	*
32	91%	*	0 (92)%	*	80%	*	0 (92)%	63%
41	88%	*	*	*	*	75%	*	*
42	*	*	*	*	*	*	*	63%
51	89%	*	*	*	*	*	*	*
52	*	*	*	*	*	*	*	*
61	*	*	*	71%	*	*	*	*
62	*	*	*	*	*	*	*	*
71	90%	*	*	77%	*	*	*	*
81	*	*	*	*	*	*	*	*
82	*	*	*	*	*	*	*	*
91	*	*	*	62%	*	49%	0 (91)%	0 (91)%
92	*	*	*	70%	*	70%	*	*

Note: “*” = 100% Kappa Result
() = percent agreement

Table 3: Kappa Results From Form-III (Test Result Entry Form)

Mammogram Findings														Fine Needle Aspiration Findings		
Abs ID	Cat ¹ I Right	Cat II Right	Cat III Right	Cat IV Right	Cat V Right	Cat VI Right	Cat I Left	Cat II Left	Cat III Left	Cat IV Left	Cat V Left	Cat VI Left	Resolved/ Not bloody	Bloody Fluid	Residual Mass	
11	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
12	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
21	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
22	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
31	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
32	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
41	*	*	*	*	*	*	0 (80)%	*	*	*	*	*	*	*	*	
42	0 (75)%	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
51	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
52	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
61	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
62	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
71	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
81	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
82	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
91	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
92	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	

Note: Cat¹ = Category
 “*” = 100% Kappa Result
 () = percent agreement

Table 4: Kappa Results From Form-IV (Followup Form)

Abs ID	Undocumented	Routine Screening	12 month CBE	12 month mammo	Immediate Mammo	Extra Views	Cone Compression	Magnification Views	Interval Mammo	Interval CBE	Ultra-sound	Surgical Referral
11	83%	87%	*	*	*	*	*	*	*	*	*	0 (88)%
12	73%	78%	*	*	*	*	*	*	*	*	*	*
21	*	*	*	*	*	*	*	*	*	*	*	*
22	*	*	*	*	*	*	*	*	*	*	*	*
31	83%	*	0 (95) %	*	*	*	*	*	*	0 (95)%	*	*
32	*	*	*	*	*	*	*	*	*	*	*	*
41	66%	*	*	81%	*	*	*	*	*	*	*	*
42	*	*	*	*	*	*	*	*	*	*	63%	*
51	*	*	*	*	*	*	*	*	*	*	*	*
52	*	*	*	*	*	*	*	*	*	*	*	*
61	*	*	*	*	*	*	*	*	*	*	*	*
62	*	*	*	*	*	*	*	*	*	*	*	*
71	*	*	*	82%	*	*	*	*	*	*	*	*
81	*	*	*	*	*	*	*	*	*	*	*	*
82	*	*	*	*	*	*	*	*	*	*	*	*
91	*	*	*	*	*	*	*	*	*	*	*	*
92	*	*	*	*	*	*	*	*	*	*	*	*

Note: “*” = 100% Kappa Result
() = percent agreement

Table 5: Kappa Results from Form-IV (Followup Form) -Surgeon's Letter

Abstractor ID	Surgeon's Letter			
	Further Tests	Evidence of Malignancy	Followup in Primary care office	Followup in Surgeon's office
11	*	*	*	*
12	*	*	*	*
21	*	*	*	*
22	*	*	*	*
31	*	*	*	*
32	*	*	*	*
41	*	*	0 (93)%	*
42	*	*	*	*
51	*	*	*	*
52	*	*	*	*
61	*	*	*	*
62	*	*	*	*
71	*	*	*	*
81	*	*	*	*
82	*	*	*	*
91	*	*	*	*
92	*	*	*	*

Note: "*" = 100% agreement
 () = percent agreement

YEAR TWO

Table 1: Kappa Results From Form-I (General Information Form)

Abstractor ID	Eligibility Code	Date Most Recent Office Visit (Q2)	Total Number of Visits Within 15 Months (Q3)	Total Breast Care Related Encounter(s)
11	85.4%	*	*	74%
12	87.4%	*	85%	82.4%
21	*	75%	75%	61%
22	*	*	*	*
31	*	87.5%	58.9%	70%
41	69%	*	85.5%	85%
42	*	*	86.4%	71.9%
51	*	*	62%	83%
61 [#]	*	*	82.9%	*
62	*	89%	61%	*
71	*	90%	71.7%	*
81	86.2%	*	84.9%	77.8%
82	*	82%	89%	76.6%
91	*	85.7%	*	61%
92	*	89%	87%	71%

Note: “*” = 100% Kappa Result

“[#]” = we conducted two quality controls with this abstractor. Her kappa for first quality control was unacceptably low. Therefore we gave her further instructions about abstraction and asked her to go back and review all her charts. The kappa results shown here are calculated based on the second quality control.

Table 2: Kappa Results From Form-II (Visit Entry Form)

Abstractor ID	Type of Contact (Q6)	Symptom Lump R (Q9)	Symptom Lump L (Q9)	CBE Documentation			Abnormal Lump R (Q11)	Abnormal Lump L (Q11)
				Inspection (Q11)	Palpation (Q11)	Lymph Node Exam (Q11)		
11	*	*	*	0 (91%)	*	*	*	*
12	*	*	*	0 (90)%	*	*	*	*
21	*	*	*	60%	*	*	*	*
22	*	*	*	46%	*	0 (86%)	*	*
31	*	*	*	*	*	*	*	*
41	*	*	*	*	*	*	*	*
42	*	*	*	*	*	*	*	*
51	*	*	*	*	*	*	*	*
61	*	*	*	*	*	0 (91%)	*	*
62	*	*	*	*	*	*	*	*
71	*	*	*	*	*	*	*	*
81	*	*	*	*	*	*	*	*
82	*	*	*	*	*	*	*	*
91	*	*	*	*	*	*	*	*
92	*	*	*	*	*	*	*	*

Note: “**” = 100% Kappa Result
() = percent agreement

Table 3: Kappa Results From Form-III (Test Result Entry Form)

Abs ID	Mammogram Findings												Fine Needle Aspiration Findings		
	Cat ¹ I Right	Cat II Right	Cat III Right	Cat IV Right	Cat V Right	Cat VI Right	Cat I Left	Cat II Left	Cat III Left	Cat IV Left	Cat V Left	Cat VI Left	Resolved/ Not bloody	Bloody Fluid	Residual Mass
11	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
12	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
21	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
22	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
31	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
41	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
42	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
51	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
61	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
62	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
71	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
81	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
82	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
91	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
92	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*

Note: Cat¹ = Category
 “*” = 100% Kappa Result

Table 4: Kappa Results From Form-IV (Followup Form)

Abs ID	Undocu-mented	Routine Screening	12 month CBE	12 month mammo	Mammo Recomm	Extra Views	Cone Compression	Magnification Views	Interval Mammo	Interval CBE	Ultra-sound	Surgical Referral
11	*	*	*	*	*	*	*	*	*	*	*	*
12	*	*	*	*	*	*	*	*	*	*	*	*
21	*	*	*	*	*	*	*	*	*	*	*	*
22	*	*	*	*	*	*	*	*	*	*	*	*
31	*	*	*	*	*	*	*	*	*	*	*	*
41	*	*	*	*	*	*	*	*	*	*	*	*
42	*	*	*	*	*	*	*	*	*	*	*	*
51	*	*	*	*	*	*	*	*	*	*	*	*
61	*	*	*	*	*	*	*	*	*	*	*	*
62	*	*	*	*	*	*	*	*	*	*	*	*
71	*	*	*	*	38% ¹	*	*	*	*	*	*	*
81	*	*	*	*	*	*	*	*	*	*	*	*
82	*	*	*	*	56.2%	*	*	*	*	*	*	*
91	*	*	*	*	*	*	*	*	*	*	*	*
92	*	*	*	*	*	*	*	*	*	*	*	*

Note: “*” = 100% Kappa Result

() = percent agreement

“1” = asked the abstractor to review all her entries regarding mammography recommendation, due to low kappa

Table 5: Kappa Results from Form-IV (Followup Form) - Surgeon's Letter

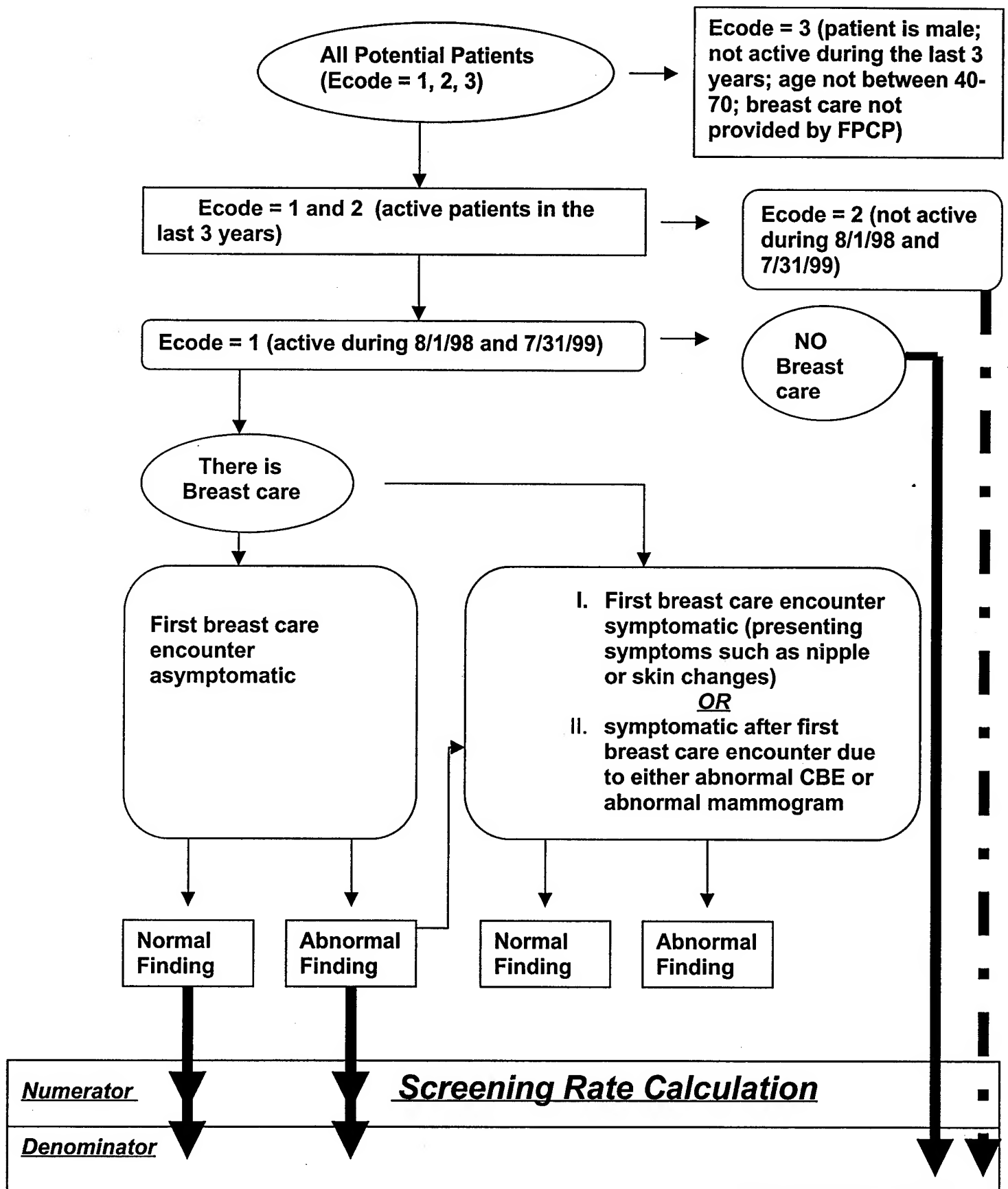
Abstractor ID	Surgeon's Letter			
	Further Tests	Evidence of Malignancy	Followup in Primary care office	Followup in Surgeon's office
11	*	*	*	*
12	*	*	*	*
21	*	*	*	*
22	*	*	*	*
31	*	*	*	*
41	*	*	*	*
42	*	*	*	*
51	*	*	*	*
61	*	*	*	*
62	*	*	*	*
71	*	*	*	*
81	*	*	*	*
82	*	*	*	*
91	*	*	*	*
92	*	*	*	*

Note: "*" = 100% agreement

APPENDIX 19

Screening Rates Baseline Year, 5/1/98-7/31/99

Figure 1: Logistic Flow Chart



BASELINE YEAR 5/1/98 - 7/31/99

Breast Cancer Screening Rates By 2 Age Groups (40-49, >= 50) For Individual Site

	Site 5 (Prelim)			Site 9 (Prelim)			Site 10 (Prelim)			Site 11 (Prelim)		
	40-49	>= 50	Total	40-49	>= 50	Total	40-49	>= 50	Total	40-49	>= 50	Total
CBE ordered	53.2%	66.6%		52.1%	59.2%		52.7%	57.3%		39.8%	61.3%	
CBE done	52.8%	64.5%		52.1%	59.2%		52.7%	56.2%		39.8%	61.3%	
Mammo ordered	42.9%	67.6%		29.6%	40.0%		42.3%	48.6%		30.8%	45.2%	
Mammo done	39.0%	65.5%		30.0%	57.3%		36.9%	56.7%		28.2%	47.6%	
Both done	34.2%	56.1%		23.9%	42.0%		31.1%	44.5%		24.1%	44.4%	
Total n = (for												
Ecode = 1 only)	231	287	518	257	262	519	226	366	592	118	124	242
Total n = (for all												
patients)	436	494	930	446	396	842	290	476	766	141	157	298

	Site 8 (Prelim)			Site 12 (Prelim)			Site 3			Site 6		
	40-49	>= 50	Total	40-49	>= 50	Total	40-49	>= 50	Total	40-49	>= 50	Total
CBE ordered	48.7%	58.5%		41.3%	56.1%		50.6%	65.0%		55.0%	54.5%	
CBE done	48.7%	53.2%		36.5%	50.0%		44.0%	59.9%		49.2%	41.5%	
Mammo ordered	41.6%	57.8%		32.8%	55.7%		51.8%	72.7%		35.6%	49.5%	
Mammo done	41.6%	65.5%		25.6%	56.7%		41.5%	60.8%		24.4%	40.0%	
Both done	26.3%	41.4%		16.8%	35.1%		25.9%	45.1%		19.0%	27.3%	
Total n = (for Ecode = 1 only)	193	232	425	126	97	223	173	225	398	315	338	653
Total n = (for all patients)	389	483	872	215	151	366	242	298	540	435	436	871

	Site 1			Site 7 (Prelim)			Site 4 (Prelim)			Total		
	40-49	>= 50	Total	40-49	>= 50	Total	40-49	>= 50	Total	40-49	>= 50	Total
CBE ordered	26.9%	30.6%		49.2%	58.6%		52.0%	45.2%		48.7%	54.5%	
CBE done	25.8%	28.1%		47.5%	56.1%		50.8%	45.0%		46.7%	52.1%	
Mammo ordered	33.6%	55.3%		41.3%	57.6%		54.7%	53.5%		41.5%	55.2%	
Mammo done	21.7%	34.0%		31.7%	55.3%		31.5%	38.6%		31.5%	50.7%	
Both done	13.7%	19.7%		24.8%	43.9%		22.7%	28.1%		23.8%	37.9%	
Total n = (for Ecode = 1 only)	259	246	505	480	576	1056	519	825	1344	2897	3578	6475
Total n = (for all patients)	467	429	896	748	909	1657	897	1037	1934	4706	5265	9971

* Prelim = screening CBE or mammograms for women with any abnormalities during the study period are not included

APPENDIX 20

Knowledge, Attitude and Behavior Scale Pre; Post vs. Reassessment Results

THREE SURVEYS (N = 91) ALL IN PERCENTAGE

All 5 sites individually Question 1

Site	Correct Pre	Correct Post	Correct Reass	Correct Post&Reass	retention	Wrong Reass
6	80	100	67	67	67	33
7	58	88	71	63	71	29
8	45	91	64	64	70	36
9	69	100	54	54	54	46
10	62	88	69	62	70	31
<hr/>						
TOTAL (n=91)	59	91	66	62	67	34

All 5 sites individually Question 2

Site	Correct Pre	Correct Post	Correct Reass	Correct Post&Reass	retention	Wrong Reass
6	67	100	50	50	50	50
7	79	100	75	75	75	25
8	55	100	91	91	91	9
9	54	100	62	62	62	38
10	81	96	88	85	88	12
<hr/>						
TOTAL (n=91)	69	99	79	78	79	21

All 5 sites individually Question 3

Site	Correct Pre	Correct Post	Correct Reass	Correct Post&Reass	retention	Wrong Reass
6	83	100	100	100	100	0
7	83	96	100	96	100	0
8	77	95	95	91	95	5
9	62	92	92	85	92	8
10	100	100	92	92	92	8
<hr/>						
TOTAL (n=91)	84	97	96	92	95	4

All 5 sites individually Question 4

Site	Correct Pre	Correct Post	Correct Reass	Correct Post&Reass	retention	Wrong Reass
6	83	100	17	17	17	83
7	71	58	63	38	64	38
8	32	64	41	32	50	59
9	38	62	31	15	25	69
10	27	58	46	23	40	54
<hr/>						
TOTAL (n=91)	45	63	45	27	44	55

All 5 sites individually Question 5

Site	Correct Pre	Correct Post	Correct Reass	Correct Post&Reass	retention	Wrong Reass
6	17	67	67	50	75	33
7	38	50	50	33	67	50
8	27	41	32	14	33	68
9	38	54	8	0	0	92
10	31	65	31	31	47	69
<hr/>						
TOTAL (n=91)	32	54	35	24	45	65

All 5 sites individually Question 6

Site	Correct Pre	Correct Post	Correct Reass	Correct Post&Reass	retention	Wrong Reass
6	33	50	50	50	100	50
7	71	88	75	75	86	25
8	36	62	43	33	54	57
9	46	54	46	38	71	54
10	73	85	65	65	77	35
<hr/>						
TOTAL (n=91)	57	73	59	56	76	41

All 5 sites individually Question 7

Site	Correct Pre	Correct Post	Correct Reass	Correct Post&Reass	retention	Wrong Reass
6	33	33	33	17	50	67
7	50	100	63	63	63	38
8	36	62	43	33	54	57
9	46	69	38	31	44	62
10	38	38	46	31	80	54
<hr/>						
TOTAL (n=91)	42	64	48	39	60	52

All 5 sites individually Question 8

Site	Correct Pre	Correct Post	Correct Reass	Correct Post&Reass	retention	Wrong Reass
6	33	100	67	67	67	33
7	48	92	63	63	68	38
8	55	76	67	57	75	33
9	54	62	69	46	75	31
10	38	81	77	69	86	23
<hr/>						
TOTAL (n=91)	47	81	69	61	75	31

All 5 sites individually Question 9

Site	Correct Pre	Correct Post	Correct Reass	Correct Post&Reass	retention	Wrong Reass
6	83	100	83	83	83	17
7	79	100	96	96	96	4
8	100	100	95	95	95	5
9	77	77	92	69	90	8
10	85	96	88	84	88	12
<hr/>						
TOTAL (n=91)	86	96	92	88	92	8

All 5 sites individually Question 10

Site	Correct Pre	Correct Post	Correct Reass	Correct Post&Reass	retention	Wrong Reass
6	67	67	50	50	75	50
7	46	100	92	92	92	8
8	38	90	76	71	79	24
9	54	85	77	69	82	23
10	46	69	65	50	72	35
<hr/>						
TOTAL (n=91)	47	84	76	69	82	24

All 5 sites individually Question 11

Site	Correct Pre	Correct Post	Correct Reass	Correct Post&Reass	retention	Wrong Reass
6	0	100	83	83	83	17
7	17	88	58	58	67	42
8	14	76	33	24	31	67
9	8	92	15	15	17	85
10	23	73	62	50	68	38
<hr/>						
TOTAL (n=91)	15	82	49	43	53	51

All 5 sites individually Question 12

Site	Correct Pre	Correct Post	Correct Reass	Correct Post&Reass	retention	Wrong Reass
6	0	67	50	50	75	50
7	21	75	29	25	33	71
8	14	68	36	36	53	64
9	15	46	8	8	17	92
10	8	38	31	15	40	69
<hr/>						
TOTAL (n=91)	13	58	30	24	42	70

All 5 sites individually Question 13

Site	Correct Pre	Correct Post	Correct Reass	Correct Post&Reass	retention	Wrong Reass
6	83	83	67	67	80	33
7	83	79	96	75	95	4
8	68	67	81	62	93	19
9	62	62	69	46	75	31
10	54	85	73	69	82	27
<hr/>						
TOTAL (n=91)	68	76	80	66	87	20

All 5 sites individually Question 14

Site	Correct Pre	Correct Post	Correct Reass	Correct Post&Reass	retention	Wrong Reass
6	67	100	50	50	50	50
7	42	96	54	50	52	46
8	27	86	27	23	26	73
9	42	92	46	46	50	54
10	54	92	42	38	42	58
<hr/>						
TOTAL (n=91)	43	92	43	40	43	57

All 5 sites individually Question 15

Site	Correct Pre	Correct Post	Correct Reass	Correct Post&Reass	retention	Wrong Reass
6	83	100	100	100	100	0
7	79	100	96	96	96	4
8	45	91	73	68	75	27
9	58	100	92	92	92	8
10	69	96	85	85	88	15
<hr/>						
TOTAL (n=91)	66	97	87	86	89	13

All 5 sites individually Question 16

Site	Correct Pre	Correct Post	Correct Reass	Correct Post&Reass	retention	Wrong Reass
6	67	100	100	100	100	0
7	88	100	92	92	92	8
8	91	95	100	95	100	0
9	77	85	77	69	82	23
10	69	96	96	92	96	4
<hr/>						
TOTAL (n=91)	80	96	93	90	94	7

All 5 sites individually Question 17

Site	Correct Pre	Correct Post	Correct Reass	Correct Post&Reass	retention	Wrong Reass
6	0	50	33	0	0	67
7	46	75	54	46	61	46
8	14	73	36	32	44	64
9	23	54	38	23	43	62
10	42	81	38	31	38	62
<hr/>						
TOTAL (n=91)	31	71	42	32	45	58

All 5 sites individually Question 18

Site	Correct Pre	Correct Post	Correct Reass	Correct Post&Reass	retention	Wrong Reass
6	33	67	100	67	100	0
7	71	83	96	79	95	4
8	64	73	41	27	38	59
9	77	85	62	54	64	38
10	65	73	77	62	84	23
<hr/>						
TOTAL (n=91)	66	77	73	57	74	27

All 5 sites individually Question 19

Site	Correct Pre	Correct Post	Correct Reass	Correct Post&Reass	retention	Wrong Reass
6	83	80	0	0	0	100
7	63	92	75	75	82	25
8	67	86	64	55	63	36
9	50	77	54	46	60	46
10	73	92	73	69	75	27
<hr/>						
TOTAL (n=91)	66	88	64	60	68	36

APPENDIX 21

Patient Instructor Pre vs. Reassessment and Post vs. Reassessment Results

TEACHING LIVE MODEL BREAST EXAMINE TECHNIQUE PRE VERSUS REASSESSMENT

Site Number	% of the breast area examined			p-value
	Pre	Reassessment	Improve	
6	92.1	96.8	4.7	0.2376
7	79.8	98.5	18.7	0.0045
8	89.4	95.2	5.8	0.0593
9	87.3	85.8	-1.4	0.793
10	90.7	93.8	3	0.2482

All 5 Sites	87.2	94.4	0.7	0.0009
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BOLD FACE indicates statistically significant with p-value less than .05

Score on Palpation (out of 5)				% who score a 5 out of 5	
Pre	Reassessment	Improve	p-value	Pre	Reassessment
4.2	4.6	0.4	0.3873	75	81.2
2.9	4.6	1.7	<0.0001	32	80
3.2	4.6	1.3	<0.0001	33.3	79.2
3.8	4.3	0.4	0.2144	53.3	73.3
3.5	4.2	0.7	0.0018	40.7	72.2

	3.4	4.5	1	<0.0001	41.4	76.7
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TEACHING LIVE MODEL BREAST EXAMINE TECHNIQUE POST VERSUS REASSESSMENT

Site Number	% of the breast area examined		
	Post	Reassessment	Improve
6	98.7	99.1	0.3
7	99.1	98.6	-0.4
8	99.4	95	-4.4
9	94.9	85.8	-10.1
10	98.6	93.8	-5.4

All 5 Sites	98.4	94.3	-4.1
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BOLD FACE indicates statistically significant with p-value less than .05

Post	Score on Palpation (out of 5)			% who score a 5 out of 5	
	Reassessment	Improve	p-value	Post	Reassessment
4.3	4.6	0.3	0.6595	83	75
3.6	4.6	0.9	0.0017	54	80
4.5	4.6	0	0.5847	82.6	78.3
4.5	4.2	-0.3	0.2554	75	71.4
4.4	4.1	-0.3	0.2088	54.8	66.7

4.2	4.4	0.2	0.1379	66.9	74.7
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APPENDIX 22

Silicone Breast Model Pre vs. Reassessment and Post vs. Reassessment Results

SILICONE BREAST MODEL SENSITIVITY AND SPECIFICITY
PRE TRAINING TESTING RESULTS VERSUS REASSESSMENT TESTING RESULTS

Site Number	Sensitivity(%)			
	Pre	Reassessment	Improve	p-value
6	64.28	61.75	-2.4	0.7534
7	70.1	65.32	-6	0.086
8	54.1	59.29	6.3	0.3178
9	46.9	61.25	14.4	0.0036
10	61.5	56.2	-5.8	0.2283
All 5 Sites	59.8	60.47	0.52	0.8266

BOLD FACE P-VALUES are statistically significant at cut-off less than .05

	Specificity(%)			
	Pre	Reassessment	Improve	p-value
	21.4	58.4	42.9	0.022
	14.6	45.2	31.75	<0.0001
	25.5	47.9	22.3	0.0007
	26.8	46.9	18.7	0.0396
	23.1	53.3	35.5	<0.0001
	20.61	49.36	29.23	<0.0001

SILICONE BREAST MODEL SENSITIVITY AND SPECIFICITY

POST TRAINING TESTING RESULTS VERSUS REASSESSMENT TESTING RESULTS

Site Number	Sensitivity(%)			p-value
	Post	Reassessment	Retention	
6	67.5	61.7	-3.6	0.3992
7	70.2	65.3	-6.1	0.0404
8	54.8	59.3	5.7	0.1763
9	61.5	61.2	-0.2	0.9651
10	62.9	56.2	-6.9	0.0928
All 5 Sites	62.8	60.5	-2.2	0.2166

BOLD FACE P-VALUES are statistically significant at cut-off less than .05

Post	Specificity(%)		p-value
	Reassessment	Retention	
25	58.4	41.7	0.007
45.1	45.2	1.3	0.8515
29.7	47.9	18.1	0.0039
30	46.9	15.5	0.0169
25.4	53.3	26.9	0.0004
32.3	49.4	17.22	<0.0001

APPENDIX 23

Focus Group Results

**Consent to participate in a study:
Improved Follow-up of Breast Abnormalities Through Comprehensive
Breast Care in Women 40 to 70 Years of Age**

MAY 15 1998

Introduction

The Departments of Family Practice, Epidemiology, and Surgery at Michigan State University (MSU) are working with the directors of the MSU Family Practice Residency Programs to develop a model curriculum in comprehensive breast care. The curriculum has been tested in other settings and now we want to evaluate its performance in a residency setting to assess if it performs better than the current educational approach. To accomplish this, your director has agreed to make this newly developed curriculum for primary care physicians a required component of your residency training. The curriculum is made up of formal lectures, videotapes, and "hands on" learning with silicone models and live models. Additionally, we will be providing chart reminders to assist in your care of women over the age of 40.

Procedures

To assess the effectiveness of the educational program, we will administer tests before and after the training sessions. We will use specially trained live models to assess your ability to properly perform a clinical breast examination. We will also be abstracting medical records of women over age 40. The information we collect will be used to see how well the training program performed in the residency setting.

Confidentiality

In order to preserve your confidentiality, the data we collect will not have any personal identifiers, but only study identifiers so we can link the information over time. All data will be pooled with that of other learners participating in the study. If you wish, upon completion of the study and data analysis, a summary will be made available to you. If you wish to receive a copy of the results, please fill out a postcard with your name and address.

Risk of participation

There are no physical risks associated with participation in this study. We do not intend to make your performance known to others. Some learners become anxious when formal evaluations are performed. Other than this, we know of no other discomfort you might experience due to participation in the study.

Benefit of participation

The benefit to you is unclear. If this program is a more effective learning model than standard approaches then by participating in the training sessions, the project will benefit you directly by enhancing your knowledge and skills for comprehensive breast care. Additionally, your colleagues will derive benefit from its use in the future.

While you have no choice in participating in the training program (it is a requirement of your residency), you do have the choice of allowing us to use and analyze your test results along with those of your colleagues. You are being asked to give us permission to use this data for the purposes of study and dissemination to other medical educators. If you decide that we cannot use your data, you will still participate in the educational program. Your director will not be asked to influence your decision to participate. Your participation is voluntary.

If you have any questions about this study, please contact the principal investigator, Dorothy Pathak, Ph.D. at Michigan State University, 517-353-0772.

Your signature indicates that you voluntarily participate in the research component of this project. You allow us to use the assessment tools as the data for the project.

**IRHS APPROVAL FOR
THIS project EXPIRES:**

**SPARROW HOSPITAL IRR
APPROVAL FOR THIS PROJECT
EXPIRES:**

Signature _____

Form revised: April 21, 1998

JUN 4 2000 Date

SUBMIT RENEWAL APPLICATION

FEB 14 2001

PHYSICIAN TRAINING REASSESSMENT

Site Specific Focus Group Feedback

Physician Training Reassessment Sessions

Sparrow Hospital /MSU - St. Lawrence Campus Family Practice Residency Program/ :	May 4, 2000
MidMichigan Regional Medical Center Family Practice Residency Program	May 18, 2000
Saginaw Cooperative Hospitals, Inc. Family Practice Residency Program	May 19, 2000
Sparrow Hospital/MSU Family Practice Residency Program	June 8, 2000
Kalamazoo Center of Medical Studies Family Practice Residency Program :	June 9, 2000

-- Feedback is herein provided by question, by site, in the order by which those sites were visited. Each site had 2 back-to-back hour-long focus groups that were to provide feedback about their extensive day-long training during the previous 12 months as part of a breast care research study.

-- Method of recording at all sites was two-fold: 120-minute audio tapes and Panasonic tape recorder as well as handwritten (not shorthand) notes from the recorder/transcriber/editor

-- Questions were posed by the moderator in a way to encourage discussion/ feedback from all participants. During some of the focus groups, discussion was free-flow. In most cases the sequence of the prepared questions was not strictly followed and the moderator allowed random discussion. However, for all sites after the first one (where participants were very reticent and hesitant to speak- possibly intimidated by the tape recorder) the moderator polled each participant for questions 8,9 & 10 in which she requested negative and positive feedback about the initial training sessions. Responses often overlapped other question issues and may not be strictly or exclusively related to the subject under which they are recorded. Transcription is not verbatim but all significant feedback IS on record in these pages.

- - represents a new speaker.
- Participants/speakers are not identified by name, however in some instances the gender or the role (faculty or resident) of the speaker was relevant to the feedback.
- Of the 10 groups, participants ranged in number from 3 to 14. The dynamics in each group – even within the same agency - was often surprisingly different. In one agency, the feedback from one group with regard to seated position exam and chart guidelines was totally contracted by its second group.
- *italicized* text represents either the moderator or the recorder/editor (ed)
- [brackets] are editor's points of clarification.

- mrs 8/3/00 -

SUMMARY OF FOCUS GROUP RESPONSE BY SITES

1. RELEVANCE OF THE CURRICULUM TO DAILY PRACTICE:

ST LAWRENCE/SPARROW- Q1:

- Changed how I note my findings, became much more standardized; made clearer how to handle lumps; practicing on silicone models helped.
- Being an intern, I didn't have lots of patients and didn't get chance to use it.
- Workshop was excellent; but didn't get a chance to use it much.
- Absolutely useful; last time such instruction was in med school – gave me some set things to keep in mind; to me the mammogram was the standard by which I was going to find the pathology and I left with a lot of different ideas than what I started with.
- Very helpful in deciding what needs to be evaluated and what you can skim.
- Actual clinical skills part seemed to be the most helpful and seemed to stick the best.
- Had confidence in my cbe knowledge that I didn't have before the workshop when I worked with a surgeon and did 7-9 breast exams a day.

MIDLAND - Q1

- The curriculum definitely changed my exam. Having them sit up changed, but I don't know whether it would be more useful.
- Having the Gail model there was helpful.
- Flushed my exam out a little.
- I do a more efficient exam; never did a seated exam before, not do it more consistently.
- Algorithms helped, as well as the pink sheets in the charts. They kind of make sure that you're doing what's most logical next.
- I've been more careful in my documentation and history dictation
- I missed the first training session but I've been using the pink sheets and have done more breast aspirations.
- Got me started using the Gail model, but I've fallen away from that.
- Have never looked at those sheets. Ever!

SAGINAW - Q1

- Comfort level in terms of feeling like I know what I'm going to feel when I'm actually feeling it has been significantly improved.
- I use a lot of it for teaching and instruction
- A great course
- Content was excellent; it reaffirmed what I was already doing
- I have done less than 10 breast exams since we've had this. Being a 1st year, I have clinic only once a week and don't have a lot of patients so I easily forget what I learned.
- No follow-up difference

SPARROW/ST. LAWRENCE - Q1

- I followed guidelines; attempted aspirations; referred to surgeon. Did not get any note from the surgeon and I can't remember if we had any follow-up after that.
- I tend to get all the female patients in our clinic.
- Used the curriculum some for masses or pain, discharges
- I did lots of breast exams but didn't find any abnormalities.

- It changed the way I did a breast exam. Every time I did a breast exam I would recall the experience I had here and it would kind of focus me into being a little more thorough. I think I did a decent job beforehand, but I do an even better job now. It acts as a reminder of thorough technique.
- Previous to this when I found a breast mass I did a surgical referral. After having done this [the course], I took control.
- My patient population tends to be young healthy females, so you're not going to find much.

Group II.

- Increased the comfort level on doing CBE's in my practice, allowing for better communication.
- I used the didactic information
- The course made me consider fine needle aspirations
- It was helpful for me to deal with the issue of breast pain.

[ed: In contrast to some of the other sites, almost all participants had done CBE's and 4 had found abnormalities.]

KALAMAZOO - Q1

- Have been doing better breast exams - more thorough
- Better patient education particularly of risk factors
- I use the flow sheets that are in the charts
- Have had an abnormality of a bloody nipple discharge and used flow sheet
- The flow sheet helped me confirm an abnormality
- Patient appreciated the follow up.

Group II

- It was very helpful. I now do my breast exams differently than I did before and so now I have a system and a pattern and I feel very good about it.
- It changed how I did the inspection part of the exam but mostly, having already been trained at MSU, I'm already doing the breast exam the way they trained us to it last time.

2. IMPACT ON PROFESSIONAL EFFECTIVENESS IN BREAST CANCER SCREENING AND F/U OF ABNORMALITIES

ST LAWRENCE/SPARROW - Q2:

- more comprehensive; added about 30 second more time in exam and 30 seconds in documentation;
- picked up one abnormality; emphasis on symmetry helped a lot;
- found a couple of abnormalities but nothing much done differently than would have been done before the trig.
- more time spent on switching pattern and incorporating a different approach; more comfortable with my diagnosis – what help
- the workshop didn't affect my "underpinnings" of the breast exam

MIDLAND - Q2

- The course gave a nice framework for FU. Now I'm more streamlined when I talk to my patients with abnormalities – I have a number of them.
- Helped me develop a standard for screening
- Gave me the available data/percentages or whatever, to "talk" to the patients. I've been able to use that effectively.
- New data coming up all the time; some kind of ongoing updated material would be helpful.

SAGINAW - Q2

- I was much more aggressive with the follow-up. I think education-wise it was nice to explain to the patient the 3 things.
- I found a lump and was directed to refer it to the surgeon – but I knew what to do.
- What I like is the pink sheet. I use those a lot especially for breast lumps when I get a report back of a suspicious lump I go to the chart and say, OK, we go from here to here with a logical step-by-step progression.
- I feel quite confident when I do a breast exam using the pink sheet.
- Some of the information was a little new but as far as changing practice, it makes no difference.

SPARROW/ST. LAWRENCE - Q2

- Part of what you see more and more now is that patients don't need to have a referral or get a mammogram completed with anybody else's recommendation – they just do them on their own. What I'm seeing is a lot of my female older patients getting their mammogram completed before I ever see them. They'll get a letter back from their radiologist saying they had a normal mammogram, and therefore they don't come in for the remainder of their exam, especially the post-hysterectomy patients, menopausal patients, who don't feel that a pap smear is necessary anymore because they're not having their period – they get a mammogram before they ever see me, and then as opposed to coming in for yearly exams, what they'll come in for a hypertension check in the middle of the year and I may have a report that they had a mammogram done mid-cycle, but in the midst of everything else you're doing during your day, they're not doing annual exams. The system that's in place now lends away from annual exams. Patients do more and more on their own without understanding the significance For men you don't just do a PSA and call it a day; for women you just don't do a mammogram and call it a day. The patients don't know that and what I'm seeing is a lot of patients who'd rather NOT come into the office

and see me if they can get the test done and get it over with and I'm seeing a lot of that now too. I'm getting a lot of mammogram reports without seeing patients before ever even ordering one. That's been a little change in the system and that's only been the last 2-3 years here in town that that has happened. With regard to continuity of care in this instance, we'll see how it shakes itself out over time. I still see a group of patients who are very concerned about their health care and come in quite a bit, but there's another group that's a different subset."

MODERATOR: We actually need to make a note about talking about that for curriculum revision for content for physicians to be aware of when they educate their patients about the need for having pieces together, not just a clinical breast exam in isolation of the mammogram, and the mammogram in isolation of the clinical.

Re: THE "TIME" ISSUE IN FILLING OUT THE CHART

- A lot of the forms are negative.
- If someone were to come in with lump or breast pain, that would be more likely to dictate a total breast exam, but if it's part of a complete physical, the tendency is to have a check list and just check "normal" and describe "abnormal" whether it's genitalia exam, chest exam, or whatever.
- When I used to be able to dictate, I dictated it all, now I just check, check, check, check.

KALAMAZOO - Q2

Group II

- Wow. I've done like a 100! I've done 20 this week. We do them all the time.

RE INCIDENCE OF ABNORMALITIES AND HELPFULNESS OF THE CURRICULUM

- I was doing surgery rotation and someone was referred with a mass and then I felt it and we took it out the next day and it was cancer, but I didn't find anyone with abnormalities.
- I had a patient just within the last month and I'm having her come back to recheck.
- Same thing. Just one patient. Feels like a benign mass in terms of risk factors and age and location and size. She's coming back next month for a re-check. Other than that I have had no abnormalities.

3. VALUE OF THE CLINICAL SKILLS COMPONENT: POSITION PATIENT, SKIN EXAM, LUMP ID, COMMUNICATION W/PATIENT

ST LAWRENCE/SPARROW - Q3 became more efficient

- Silicone models really helped me out to find what to worry about.
- Structure – what to do, how to walk through it, having a particular plan – was useful to me; having patient sit up was new to me.
- Reaffirm the silicone breast model usefulness: how hard or how soft a mass could be; it's different on the models than on human tissue; nice to go back and remind yourself so if you have a base to go back and check yourself, that could be a big benefit
- The hard thing for me was to work with a model: go in and say, "Hi, I'm going to examine your breasts and goodbye. I'm used to a full patient visit..... I don't feel I got patient skills for "communicating" with the models: I got information I could use in talking to patients, but didn't get communication skills
- A benefit of this program is that it sets you up for a format to communicate with patient; you feel comfortable with the issue of the breast exam.
- Without some kind of a "role" guide, without a chart, it was awkward to deal with the patient models. I just had to pretend that this was a patient of mine.
- Don't remember any communication training content in the workshop;
- no "dazzling" light went on;

MIDLAND - Q3

- With regard to "communication," there needs to be more about what you're actually doing. I need to spend probably a minute or 2 before the exam because I felt that my patients were more or less surprised that they had to sit up and put their hands above their head. That was the most difficult part of the exam, telling that that, "Now you have to lower your gown and I'm going to look at your breasts with your hands up. Before I would do an abdominal exam and move right up to do your breast exam. Patients want to know why and what you're doing.
- The sit-up position is contrary to what we've been doing before – it's an awkward time.
- Still a little difficulty with doing combined patient education and communication while doing exam.
- In my practice I don't like to ask young women to sit up and totally disrobe. IS THERE ANY EVIDENCE FOR AGE TO DO THIS?.
- [ed: Lot of discussion about sitting up] A young man examining a young female and now you're going to ask her to drop her gown because you're going to look at her breasts.... That's VERY self-conscious for a lot of people.
- SUGGESTION: We should continue to encourage nurses to make sure that patient's gown appropriately. A lot of times the gown will be opened in the back and then I give up. I'm not going to go through the whole thing again to do a seated exam: regress and go out of the room and all that.

SAGINAW - Q3 [RE SEATED POSITION]

- I was taught that beforehand and then I lay them back.
- I hadn't done that before and now I spend a lot of time telling the patient why I'm doing what I'm doing because they've never had that done before. None of my patients have questioned why I'm having them do that [sit up] but a lot of them go, "Oh, that's new!"
- [Female] I start out by telling the woman that I will teach her how to do a self-breast exam.

- In terms of efficiency I try to start out my whole conversation with, "You may not have had a breast exam similar to this," and the next time you do it, they expect the seated exam.
- I'm wondering if somebody can do a study to see if this maneuver is efficacious or sensitive enough to help or not help at all. Is there any support saying this can help early stages of breast cancer?
- Just from my MSU teaching, in my experience when I asked a woman here if she's standing or sitting when you feel the breast lump, or are you lying down. Because I have had difficulty finding a breast lump that they felt standing up, and I'm trying to find it with her lying down. She stands up and now I can find it and I did miss a breast lump the first time that way. So now I'm really careful about that. Plus when you do that, the contraction allows you to see if there's anything on the muscle.

MODERATOR INTRODUCTION TO THE "COMMUNICATION" PORTION OF Q3: Was there anything in the class, the didactic, about communication as an addition?

- When we first did the practice clinical breast exam, we got set up by the study! We were told, "go in and do a breast exam, and don't talk." And we walked in (Mary and I had the same evaluator) and she said, "You never introduced yourself; you never did this; you didn't do that....you didn't make me feel comfortable" This whole list of things. And you know that was very artificial for me. But they said, "Don't talk to the patient; just do a breast exam."
- It felt weird to me too.
- Then, we thought, well I don't care what you said, we're doing it our way. It was really funny, I went from a really bad evaluation to, "Oh, there's nothing really wrong here, you must have learned a lot in this course."

One thing that helped me [re communication] is to make sure I find out what the patient's expectations are before I start the exam. Make sure I know what she knows and what she's concerned about. Everybody's different, some people want to know everything; some nothing and I think you have to tailor your information and how you're talking to the patient. It is important to try to assess right out front which person I'm dealing with.

SPARROW/ST. LAWRENCE - Q3 Specifically re SKIN EXAM AND COMMUNICATION:

- I haven't changed my exam because the exam I learned at medical school always talked about the skin and the exterior.
- I changed my exam.

[ed: There was almost no response to the question about the communication portion of the training. Moderator had to ask several times. When asked if the group remembered having content on communication...]

- To tell you the truth, no!
- No.
- ... to explain as we go; keep a constant flow of communication; demonstrate on the patient while you do an exam; showing the patient different positions – all of this I was taught in medical school.

[ed: With regard to the seated position for patients, the group expressed no surprise or difference, even with regard to their patients' responses to the seated exam.]

- One of the things I found most useful – and I can't say that I've changed my methods or styles much since then – and I think you guys will find this more as you get done with your residency training, is that you don't get the opportunity to get a mini-symposium on something like this. It's just a real quick refresher, and not so much that it will ever change what you do as much as

it really helps make you stop and think for a minute: Am I doing this alright or not? Or Can I just tweak my exam a touch and make it better? You get those at the national conferences but there's very few of those that are actual workshops, most of it is just lectures so when you get the opportunities to do one of these very often [training sessions] so it's just a nice little fine tuning of something you're probably already doing well to begin with.

- It was very helpful in the fact that you often don't feel a lot of lumps in residency and up to this point and up to this point, just being able to go to the models and feel what the lumps feel like and compare to normal breast tissue makes you feel more confident in walking out of the room having told the patient you didn't feel anything abnormal. I had much more confidence after the workshop than before.
- In communicating with patients I now take complaints a little more seriously, knowing the gravity of it, and perhaps realizing that they needed more follow up. And being able to communicate with them about some areas that they may miss in a self-exam.
- [when asked if any of the patients were surprised by the seated exams:] It happens all the time with exclamations of, "Oh, I never had that before.
- Till you explain how to do the hands overhead and on your hips in the mirror, then it clicks.
- [female resident] No one has ever asked me to do a sitting up exam, even my ob/gyns.
- I've found that it's sometimes more comfortable when I do the sitting up part at the very beginning of the exam, and then you have time to talk about education and what to look for.
- If you explain to patients why you're doing a sitting exam, then they don't ask why, because you're saying, "I'm having you sit up because I'm looking for skin changes or skin retractions, they don't ask.
- I never knew why that's done [sitting up].
- I'm still not certain what the yield is on that, but I have done it since this training last year and I have had patients tell me, that while they understand, some of them don't like that part of it.
- I haven't had any patient object, merely express that they didn't like it.
- Retraction is generally a later finding.
- Well, choosing the right words and not saying, "Boy, they look great!" probably is crucial.
- It IS uncomfortable and obviously a gender issue.
- What's good is that you can include the whole self-exam issue in this and preface your sit-up exam with "This is how you should do it."

Re COMMUNICATION WITH PATIENTS:

- The biggest difficulty I ran into is the differing guidelines on when you should be getting mammograms. They will hear something different on the news six times this year. Without a doubt. One of it's going to be from someone who is not a physician; one from the AMA; one from a group of physicians who specialize in breast cancer; and there will be 3 others and they're going to see that on TV. The recommendations do continue to change. It's mind-boggling to keep up with. Who is recommending what? AAFP recommends a certain thing; ACS has another one; NCI has a different one. What is being paid for? I've had 2 patients ask and I can't answer the question. All I can tell them is that there are groups that recommend we start doing this annually at 40; some at 45; almost all groups recommend that we start doing this annually at 50 and that's the only honest answer you can give them. And hopefully they say, "what do you recommend?"
- I just use a standard I feel comfortable with and I just start mammograms at 40.
- Medicare starts at 65.
- Yea, and stops at 70!

- The curriculum helped me think about what I thought was best, pick my approach and be able to explain why I start at 40.

KALAMAZOO - Q3

Re SEATED POSITION:

- I used the seated position exam as an opportunity for patient education.
- Seated position made a difference when looking for breast symmetry.
- Silicone models gave me finger cramps I had to push so hard and they don't feel like real breasts.
- I didn't think the silicone models were helpful.

MODERATOR: How did the curriculum enhance your daily practice?

- Everything was right there. I was able to do a more comprehensive exam.
- With my patients I've found that most lumps are discovered by self exam. The curriculum has enabled me to confidently and more thoroughly educate my patients to perform self exams and risk factors.

Group II

- I learned that in med school too, the sitting, looking, doing this, but I don't do it and I've never seen anyone else that does it either unless there's a specific area of concern.
- I don't do the hands over the head very often, but I do the looking at both breasts sitting up with the hands on the hips and elbows forward.
- I actually forgot the hands over the head thing. I got reminded today. But ever since this [training] I always do it sitting up. And I noticed that I've never seen an attending do that ONCE. Out in the community, and gynecologists just don't do it. But it's funny because yesterday we learned about a patient who had dimpling that was noticed on her and it was an aggressive tumor that they found just within the last week. And I'm wondering if during the screening if they SAT her up and had her do that if they would have found it earlier because it's going to be a bad situation for her. I don't know if it's going to make a difference. I assume someone studied it and it decided that it does make a difference so that's why I do it and it doesn't seem to bother the patients at all. And I know I get a good lymph node exam out of it.
- I always do a skin exam; it's like second nature to all of us.
- [with re communication] I've always been taught that you should always tell the patient everything that you're doing. That hasn't changed.

4. BARRIERS IN APPLYING CONTENT LEARNED IN DAILY PRACTICE

ST LAWRENCE/SPARROW -Q4:

- One of the good things about what you're taught in the course is that you don't have to change what you do in the office to accommodate and make it work.
- In terms of taking more time, I don't document everything I do – communicate more than I document
- Don't remember at all about documenting
- What I remember most about the whole course is more the workup: what do you do with an abnormality, how should the flow go, what should go first, what second, ...

MIDLAND - Q4

- Re TIME ISSUE: Reality is that you don't always do a good a job as you'd like to based on time restraints;
- 5-minute breast exam is a long time if you have ½ hour total for the whole patient exam.

SAGINAW - Q4

SPARROW/ST. LAWRENCE - Q4

- It's not an issue. Breast exam is not a very time consuming thing. Even the most thorough breast exams are pretty swift and even the follow up recommendations.... there's always time to have a patient return and do an aspiration if warranted. If anything, it helps you do it more efficiently.

KALAMAZOO - Q4

- I'm always running late.
- Yes, there is extra time involved so every little patient-related procedure needs to be looked at with an eye for efficiency. The gown for instance. A lot of patients put on the gown with the opening in back. It's time consuming to leave the room and have the patient re-dress. I think it's just as important to have the nurses involved in this training. They can do a lot to maximize efficiency in this regard.

Group II

- Re TIME BARRIERS FOR THE CBE: We're always rushed, in everything that we do, but I've never once compromised a breast exam because of time. That's the last thing I would do. I would compromise a lot of other things first.
- Yea. Same here.
- Our forms are designed to just be circled for both "sitting" and "supine" so there's not really extra time needed for documentation.

5. UTILIZING THE CHART REMINDER/GUIDELINE SYSTEM FOR SCREENING AND F-U

ST LAWRENCE/SPARROW - Q5

- used it when precepting w/ residents; worked better than anything else I can remember; worked better than anything else I can remember
- I like the chart reminders because it has the algorithms on it.
- I haven't seen them.
- Are we supposed to be putting them in the charts? Because I can tell you that at Mason I've probably done 6 ppb over the last 6 months and not one patient has had a pink thing in the chart!

MIDLAND - Q5

- I use our own flow sheet; never looked at the pink sheet at all.
- I resent that it now takes me one sheet longer to document
- For the most part it's kind of in a nuisance spot. If it were back with the radiology, I would use it.
- Been a few cases where I've scanned the list
- Sometimes it's used to do aspirations
- I never caught on that the flow sheet was something I was supposed to be using.
- I'm not sure that it was taught in the course that we were supposed to be using that, or how to use that.
- I use it for precepting, for nipple discharge....
- I think that topic was at the end of the day....
- I thought it was very helpful
- The pink sheet I used a lot. The white chart was helpful in that you didn't have to look through your mammograms, but aside from that..... I thought it was just for the study.
- My concern with the pink sheet system is that any disease process we're going to end up with another sheet in the chart and that can't happen. We can look for one, but when the next one comes along, pap smear, for instance, it gets....
- And it has a sense of a legal document as well, "Doctor, you didn't follow your own algorithms in the chart."
- The problem I have with that going in the chart is that as soon as you get it on the chart it's out of date. I think these algorithms are something we need to follow consistently, to have a good way of approaching things as standardized, that may need to be computerized, something that can be updated very easily, and there it is, that's what we're following, and when we go to court you can say, "here's our pathway, that's what we're following, based on this, not something I made up on my own, or not something that was in the chart and way out of date.
- If you have a hundred patients per month join our practice, or thereabouts, and so, how many charts don't have them, and how long will it take for them.... None of them have them, because we purge the chart system about every two years. If the patient hasn't been seen in 2 years, off the shelf it comes. There's no ongoing process.

SAGINAW 5 – Q5

- Where is the chart reminder?
- It's buried, kind of in the middle.
- The other day I did do a breast exam and I was going to log the mammogram and I couldn't find the pink sheet, and that pink sheet is so easy, it has a tab on it. And I couldn't find it.
- I don't think in the residency charts they were put in every patient. I just looked at 270 charts of coding stuff and I bet I only saw about 5%.
- There's no way!
- Well, some of the charts are ratty and stuff and the tabs don't stick out very far.
- We don't know where to find them
- It was only the last time that I even knew there was a mammogram involved.
- Never even seen one!

GROUP II

- Oh yea! I've seen those.
- Well, the thing is nobody goes back to check radiology unless they're checking a test result, so if you're not checking a test result, nobody turns back there.
- And understand that most of the charts on the patients here in the resident's clinic are this pink. Sometime you can see the pink stickers on the chart, but it's just another sheet in the morass of sheets.
- I've looked at it in the earlier part, but I haven't really used it in documentation
- It should be a part of your practice and it should already be in the format that it is here.
- There is so much stuff in the charts that get buried, I think sometimes we might be overwhelmed..

SPARROW/ST. LAWRENCE -Q5

- I'm always thinking about health screening stuff with my patients, so I never noticed.
- I used the pink guidelines for my breast pain patients.
- I noticed it in the chart but I don't know if they were in every chart...
- For me, just seeing it there triggered us of it. I wouldn't necessarily be looking for it otherwise.
- Never saw it!
- I don't even know why.... Who caused it to be there? I thought it was the insurance companies to tell you the God's honest truth. I don't remember being told that we were going to have a guideline...
- I never saw it.
- If we have a thick chart, you'll never see it. If that little tab happens to fall behind another tab, you may never see it.
- We also have yellow algorithms in our charts.
- I saw and looked at 'em, but I don't know if it changed what I would have done anyway, even following the outline I not sure if I changed a whole lot.
- I had an abnormality and I referred to the chart. I felt the mass and went to my attending, but I looked looked at the algorithm to make sure I was correct.
- I had an abnormality but didn't use either of the charts.

MODERATOR: So, even though research would indicate that putting guidelines in charts will increase screening and follow-up by 10% - 15% by primary care providers, you didn't notice them here?

- I think that's because we didn't notice them period. We didn't know they were in the charts.

- I noticed it was there, but.....
- I never notice it.
- I've seen it
- But I don't think it would have made anything click in my head, "Oh, this patient needs a breast exam. Well, if there is no exam, there's no exam. I don't see how that sheet.....
- Well, for any abnormalities, they [the CRGS] are useful to remind me that I'm doing this right, but they didn't remind me to do a breast exam.
- Your perspective that you thought they were from an insurance company is exactly what I thought....
- Because they're [the insurance companies] are always in our office doing things with our charts.
- What happens now with the HMO groups is that they all have their way they want you to do it in a more calm efficient manner, so they all have their own algorithms for how they want you to take care of your own patients. My assumption was, "Oh, this one was put in here through pick-your-favorite-insurance-company and was stuffed in the chart and I never needed to look at it for the pathways because I never found a mass myself, but at the same token I assumed it was just added. Now, if somebody would have said to me, We're going to put these algorithms in the charts for you as a reminder or to help you, then I would have wondered up front where it came from and paid more attention to it.
- I thought they told us that last year.

KALAMAZOO - Q5

- The chart reminder system is great.
- We all use them.
- They're great to practice preventive medicine.
- The chart reminder forms help pull us out of that cycle that many of us get into when we get caught up in our patients chronic illnesses.
- The CRGS is a wonderful tool for abnormalities.

Group II

- I haven't really used the CR. I see them every now and then and go, "Oh yeah"!
- I don't really use them.
- We have a pink form and my system is to use that one, and as frequently as I think of it, which is most visits, we have our list of appointments and you can scan that and say annual exam. To me that's quicker.
- In terms of flow sheets, I don't use them.
- Just being pink is really helpful.
- This will become academic and antiquated very soon here and in most clinics because of automation. It will become a non-issue and will be taken care of by computer. Which is good.

6. GAIL MODEL

ST LAWRENCE/SPARROW 6

- We never got the calculator; were supposed to get one, but they needed them and took them back and we never got them.
- not used that much in our practice
- Am more sensitized to talking to patients about their risks even though I wouldn't necessarily recommend tamoxifen
- See no value
- Some patients appreciate "real numbers" and may be influenced to accept referral if risk was higher; but would not use that number to prescribe tamoxifen.
- Numbers might just raise more anxiety and not alter morbidity and mortality.
- We thought they were giving them to us, but they said they needed them for the rest of the studies so they took them all back.
- I used it in the surgeon's office every day. We generally would have patients that were referred or a question of a breast mass. Sometimes things were done correctly (mammogram, etc.) and sometimes they weren't; and so, in just part of my talking with the patient, I would take my little calculator and regardless of what the FNA showed, go through with them their risks and what that meant to them. For the most part, I found that to be very comforting for most patients.

[ed: Some felt that they would use the calculator – if they had one -- on every patient; some thought they would use it only during a full physical, maybe once a year.]

MIDLAND 6

- We use the computer.
- I thought the study left one for every time. We have one on our team.
- Time constraints – have not used it.
- Adds 3-5 minutes at least to every patient.
- I don't always use it as part of every exam; I sometimes say I will do this and send it to you
- Sometimes we increased the anxiety of the patient when we do this (use the risk factors).
- Patients like it
- Have used it where there is already a risk factor
- In the face of a lump you wouldn't use it.
- Use it every day; gotten more efficient
- Better care
- Major time commitment

[ed: Six people in the group have EVER ROUTINELY used Gail Model.]

- I don't have time to go to the computer and punch these things out.
- What is the evidence that the Gail model helps or makes a difference?
- I add up the Gail model on patients, but I do it more for academic reasons and don't necessarily discuss it with them because the evidence just isn't out there.
- (RE: THE VALUE OF USING THE GAIL MODEL:.... your mammogram has a higher false positive rate in that [at risk] group; your exam has a higher false positive rate, and so you're more likely to actually increase their Gail model risk by putting them through biopsies that they may not need.... I don't know that it warrants it.

SAGINAW 6

- Yes, we did too! We heard you promise it too. *[several echoed sentiments.]*
- I use the Gail Model sometimes
- We don't have the calculation available to us. We have to run to another room.
- People would use it in a variety of ways. Teach.
- It's more than Tamoxifen. To me, breast cancer is every woman's worry, whether she's 20 or 17. You worry about it. At least you can make her aware of what the risk factors are, even if she has none.
- I would use it more if I had something in the room with me.
- Sometimes it depends how busy I am. If I have 17 patients in a half day clinic I will not spend very much time with the patient. If there's reasonable patient time I will go through with the patient. I plan to do this for every patient in my practice.
- A lot of times you don't have the history and you specifically ask, "Is there any breast cancer." "Oh, yeah!" and go back to your pink sheets, people, and it's not on there, and get the history filled in. And, oh, by the way, now that you've put family history it increases your potential for coding. So just doing little things like that it allows you to go and be able to go and code for a high level visit because you've done the work.
- It doesn't take a long time.
- We would use them if we had them.
- I don't use them on every single patient
- It would be nice to have one in each hall at nurse' station
- Palm Pilot or Gail Model

SPARROW/ST. LAWRENCE - Q6

- What's the Gail Model?
- I didn't get one.
- Many times I've considered using this, but I just want to know, should I be using this on every woman, should I be trying to calculate risk for it. I don't use it much. To tell you the truth I don't get much support from my attending either.
- I don't remember the specifics on any time I've every asked.
- If a patient came to me and asked how she could figure out what her risk is I would whip that out in a second, but as a routine thing I don't find it useful. Now, if someone comes and tells me that her aunt, mother, grandmother and sister had breast cancer, I'm going to send them to a breast center and they can better assess their need for Tamoxifen for preventative treatment.
- I understand that.
- Being taught the Gail model is helpful in think about what the risk factors are and the important ones, but as far as using it in practice, it's non-realistic.
- I've never seen a discussion of the Gail model independent of Tamoxifen.
- I tried to use it once but it didn't calculate
- I have had very few patients ask me what is my risk. That's a doctor term
- I have not have a single person EVER ask!
- I don't know that I would spend a lot of time trying to figure it out.
- My patients tend to be train-wrecks. When they come in to see me they're 5 years past their last visit. I will have train-wrecks forever.
- Well, the big question is, does it make any difference if I get their breast exam and I get them to have their mammogram, and I convince them to have their papsmear, and I got control of their blood pressure, and get their depression controlled, and then I control their panic attacks, and

then I control the fact that they're in an abusive relationship, and then I go ahead and deal with the fact they're having this incestuous relationship 20 years ago and it's starting to come back again.... And this is 15 minutes! I jettison the risk because I'm just desperately trying to....

- Not to mention when they did find out about their risk, their anxiety level goes sky high
- At that point I'm having a specialist come in. I'm not fielding it all by myself. They don't need risk at that point; they need treatment. Do you see what I'm saying? THAT'S when I need risk, when I'm trying to convince somebody to have a mammogram who really wants to know if they really need it. That's when the risk assessment is helpful. But if somebody is going to get the mammogram and get the stuff anyway, figuring out the risk isn't going to make any difference.
- There are certainly people for whom a risk assessment would be helpful. There are people that are looking for information and trying to get some sort of handle on it. They had a friend who had cancer and now are worried.
- Some of the patients want it for reassurance.
- Seems to me this is a disease process where people DON'T want to know the risk. Just like 45-year old men who smoke DON'T want to be told they're at high risk for heart disease.
- I'm just thinking of the model I saw today. I asked her if she smoked and she was very offended with that. "You're just supposed to be looking at my breasts."

KALAMAZOO 6

- Have not used it.
- I haven't used it either.
- Unless there's a strong family history, I don't think I'm going to be using it regularly.

Group II

- We haven't used the Gail model because we don't have the software.. the computer. We've used it here in our little workshop but we don't have it.
- I don't even remember what it is.
- I don't find – from personal experience – assessing risk for breast cancer to me is... I don't want to say meaningless, but it is such a non-significant indicator of whether someone is going to get breast cancer in my experience that I would like to treat every woman as if they have the same risk, which is HIGH!. In other words, if I use the Gail model to tell me that her risk is lower, I'm not going to treat her any differently. And if it says it's really high, I'm going to do the same thing. And if the Gail model says, "Oh my gosh, it's a miracle you don't already have it" then maybe you're going every 3 minutes. But if that's the risk that I'm taking by using it... I don't know that we have that in the clinic, and if we do it certainly hasn't been advertised.
- The patients might be interested in it if it was going to change something. Maybe them [the patients] doing their own breast exams will change things.
- But what is the Gail model going to do to change our clinical practices?

7. **HAS PRACTICE CHANGED OVERALL** [Ed: Much of feedback from questions 1-6 overlapped and therefore this question was not discussed separately and has no recorded feedback per se.] See responses to Q1 where most of the feedback to this question is addressed.

8. MOST VALUABLE COMPONENT OF THE COURSE

ST LAWRENCE/SPARROW 8

- would have been nice to have silicone models in the office (instead of the calculators) ;
- thorough review of the breast exam even though most of it was covered in my medical school;
- Gail model was interesting to learn about
- Need LESS time spent on clinical exam training
-

MIDLAND 8

- A general reminder/review of proper techniques and the fact that there's a lot out there: there's a flow sheet or diagram; and also just updating your skills, but the effect wears off quickly I think, so MAYBE AN ANNUAL REVIEW would be good idea. The first few weeks it impacted me.
- I've developed a constant and systematic way of examining a patient. Also, whenever I have a problem or get stuck I can use the handout manual.
- Course was very helpful; but if you don't do it on an annual basis I'm not sure you're going to change practices that much
- A good review and reminder about how to do a good breast exam.
- We were trained [at MSU] to do that exam, but in the interest of time I stopped having them sit up and do other stuff and just did the palpation while they were lying down; this reminded me to do the full complement of the exam. I talk to my patients a lot more while I'm doing the breast exam because it takes longer to do it this way; there's more opportunity for education.
- Helped me to develop a routine.
- I remember very little of the content of the course.
- The packet is very easy to review – I just see 1 or 2 patients a day.
- Since residents' behavior changes more easily than faculties' I find it very easy to go back to the old ways.
- Overall it was a valuable experience
- The live models were great! Their input was actually very helpful. One thing I liked when we were doing it last time with the Gail Model, when we had a few case scenarios, that would have been very helpful is to have some conflicts [that would generate discussion of what to do next or which way to go].
- I liked the critiques
- It might also be helpful to have nurses do the timing, because nurses know what's going on.

SAGINAW 8

- I didn't use the Gail model as much as I should have. Initially after the course I thought about it [ed: tape stopped with about 5 more minutes of discussion that centered around the **VALUE OF THE LIVE MODELS AND THE FEEDBACK AND HOW POSITIVE THE EXPERIENCE WAS WITH THE LIVE MODELS. ONE OF THE RESIDENTS ASKED US TO EXPRESS OUR THANKS TO MSU AND THE LIVE MODELS THAT WERE USED IN LAST YEAR AND THIS YEAR'S PROGRAM. THEY SAID THE MODELS WERE EXTREMELY HELPFUL AND VERY PROFESSIONAL. THEY LEARNED A LOT FROM THEM.** mrs]
-

SPARROW/ST. LAWRENCE -Q8

- The actual didactic, statistics, treatment, were valuable for me.
- It's always nice to review. I did my breast exams the way I did before and this was really good because when I did the exams I did some teaching with it.
- The importance of certain part of the exam, having patients sit up was something I was taught originally, but the course was something that reinforced it in my mind because I was less comfortable for me as a male physician to make this woman sit up and drop her shirt as I stared at her. But the importance of this was reinforced. And the communication with the patient because the actual model that I did an exam on the first time talked about the importance of making her feel comfortable during the exam with conversation rather than silence. Those were things I came away with.
- I thought it was all a pretty good mix. The models were good.
- I liked the algorithms. I don't know if I did it much different over the past, but it's nice to know that you are doing something logical.
- What I got most out of is just being more comfortable with the triple diagnosis and having a working knowledge of that.
- The didactic review was very helpful. Should be done every year.
- I liked the live models and the silicone models. It was nice to have feedback from somebody who has been trained and knowing if I measured up.
- I appreciated the information about the breast area that needed to be covered. And now I'm teaching my patients more and I wouldn't have done that.
- I like the opportunity to come back this year [reassessment] and get feedback. I went through the CBE more quickly because I was more confident with my exam.
- The immediate feedback from live models was extremely helpful.
- The information from the whole packet gave me a lot more confidence in my exam.
- The whole experience was positive and we should have done this sooner and with other subjects..

KALAMAZOO 8

- The best part was the didactic summary.
- Good feedback
- Slides were most impressive

Group II

- Real model feedback was the most useful and constructive for me. My system for doing it [cbe] wasn't so consistent a year ago and now it is. I'm confident and at least have a good system.

9. ADDITIONAL NEEDS/TOPICS FOR FUTURE EDUCATIONAL OFFERING

ST LAWRENCE/SPARROW 9

- I would have liked to have seen the complete breast exam portion with the model patient and observer – to use that as an educational opportunity instead of - when we did it initially, someone observed what you did, then you had all the didactics and watched to see if your exam after was different. I would have like to just have ONE exam and that you and the patient got someone to practice on, with an experienced nurse practitioner, who does a zillion of these, and at that time talk about how you explain to the patient what you're doing, how you're doing, why, and just have one block so that everyone could have 1 on 1 with a teacher and that would be neat! I would have gotten an awful lot more out of that than just walking into it and not talking pretty foreign, because you don't do that. [Faculty]
- I like that suggestion. Second that motion. That would be really helpful because there is so much normal breast findings --cystic, lumpy, ropy, dense -- so how do you sort out background noise from something important. I still think that's one of the trickiest aspects of the physical exam and to have an expert physical exam do an exam with me or right behind me, or next to me would be really appreciated. I never had that at any point in my training.
- When we were in school we had models who all had abnormal findings – a really useful tool – and a qualified professional looking over your shoulders to tell you how to find the abnormality.
- Long and tiresome
- Should have been broken up into smaller sessions
- Three model exams was overkill – didn't need to do the practice exam
- Would have liked to have learned more about procedures, e.g., aspirations
- Going through the models twice was kind of tedious – I don't think I learned anything from going 2 times.
- Liked review of clinical skills and workup of abnormalities.
- Agree that silicone models were good but still haven't felt a real abnormality
- Live models were good.
- The most beneficial part was just taking time to do it, dedicating a day to do it.
- Very Informative; good training
- Needs to be reinforced periodically
- Definitely improved my clinical breast exam
- There's a lot of good information; I also liked that there was some information regarding the different breast lumps per age on your talk and it stresses that we still find breast cancer in young woman because that's where most lawsuits come. I've become much more aggressive with younger women and that was actually a strong point of the course.
- Helped me with education
- Improved my communication with the patient.

MIDLAND 9

- I did like the feedback, clinically, from the patients.
- The important thing is knowing that these medical schools from all over the country, different backgrounds, have now a same basis, same groundwork for a preceptor. The best part of it is the live models and the feedback that you get: too hard, too soft. I would embellish that part and have those patients be even more real. Have them ask me questions: "What is my risk?" They

can operationalize information that they've garnered. Maybe there are 10 key points. Maybe there's some patient education around those key points that we could have as pre-conference information to try to read and then be faced with going into a room with even a more "live" simulated patients who ask us 3 out of the 10 key points, ASK US the question and we have to come up with a patient education around that to see if we can come up with that.

- We have a normal exam and I would like to have an exam where you actually bring a model in there, do the breast exam, and say this is what you found. You have a 15-minute appointment and do 2 or 3 of those and give details, and boy....
- The breast models themselves could give you an idea of soft, medium, hard, but we're not simulating breast exams. We're not even using models [silicone] that are real...we should be using CRP technique on them...
- It would be better to have breast models with only a couple lumps.
- You might have more than one woman, a different woman in different age groups with different concerns, and try to bring out the patient, even bring out the flow sheet; she does have a lump, so now what is your game plan.

SAGINAW 9

- A lot of studies that I've seen have written directions so that the directions are given the same every time. And that's not being done' everyone was getting different directions so the study is going to have terrible biases
- It wasn't made clear to me when I initially went into the room that I should just go in and do a breast exam like I normally do.
- I wish I had gotten my computer.

SPARROW/ST. LAWRENCE 9

- Why should I -- as a third year, after I've been doing this after 5 years, 2 years clinically as a student -- why not get me WAY earlier?
- It would be good to set up this kind of session for a second-year medical student who is going through the clinical skills courses.
- Well, it's still a refresher.
- If I look at this program now and today's session, I think it's too far away from the first one. From the sense of truly coming back and looking back over a year, I don't remember it. So, to me what makes more sense is, in one hour, you can take one of the Thursday afternoon sessions and say, let's look at the major bullet points again about what we did. Just for a quick refresher, and you could really do it in a tight, concise method. I think second year med school is a great idea, but it needs to be followed up again at intervals along the way.... This is one of those areas right now that is still too important not to hit it on a recurring basis.
- In medical school I basically had one evening with a model. There were about 6 students. Not only did we go through the breast exam but we went through the pap and pelvic exam that was all crammed into the same evening. That was your clinical skills. It's more important than that. I think before you even get to the OB/GYN clerkship it [the breast exam] should be more reinforced as it is! As much as prevention is being discussed in this country nowadays, it should be taught in medical school that way too.

In response to the moderator's comment about so many late stage cases of cancer in our own Michigan communities and why/how these cases are not being detected: Compliance is an issue too. It's not just education.

- It doesn't directly hit this program proper, but I think it's important to get the information out of this program and take this back to the HMO's and other insurance companies and stress the important of prevention. If they don't jump on the prevention bandwagon, this stuff is useless! Because it won't be done. And it won't be covered. I had a patient today who came in today 10 months after her last pap and I told her there's no reason to do it now because it's not going to be covered and we might as well wait 3 months. But that means I'm putting it back in her lap to come back in 3 months and have it done. And those are the kinds of things that are not brought out enough to the insurance companies and the important of their regimens and how tight they are sometimes. [faculty]
- I know a lot of the woman who need it most are medicare and they don't cover routine breast exams, and then you're kind of stuck with if you have someone with limited financial resources who you want to charge them to do maintenance and are they willing to do that.
- It may be worthwhile to have more of an in-service towards nursing so that when somebody is in for an annual to have them -- nurses are more regimented sometimes in getting these forms out and putting them in front of you; I remember going through the chart and seeing the pink form, but my style is to, whether I see the person for an episodic visit or an annual, is that at the end of the visit I try to quickly and as briefly as I can is talk about scheduling the annual, getting this checked and that checked. I don't spend a lot of time on it, but I write in the note: Advise patient to..... So I get out of the habit of thumbing through for a pink sheet. It's hard enough to thumb through the charts. But if I found out that the nurses have it and she says, "You're doing a breast exam, here's the sheet" then I would be more likely to address the Gail model.
- I appreciate all the hard work but I think the pink sheet is kind of a waste. I enjoyed having it as part of the packet, but I think that was kind of a waste of time.
- The silicone models were unrealistic. Too many lumps.
- Live models – I realize that there was a study perspective as far as what are we actually doing when we go I there; but from a learning perspective, a 1-patient encounter on the afternoon of the training didn't do anything as far as my learning experience. I found more benefit from doing abnormal silicone breast models even though they weren't realistic.
- It would have been helpful for me to have a very concise review about a week or 2 later. You get this barrage of information and then the notebook goes on your shelf.
- The timing was overwhelming (I'm a first year resident and it was July and it was a lot of information.) If it had come later in the year I would have gotten more out of it because it was the first month of residency.
- Would have wanted feedback about my test from the silicone models.
- We were not given enough information about the scenario with the live models. I went in just to do a breast exam – didn't think of it in a clinical setting or continuity of care. When I went back for my evaluation, I was criticized for not talking, for not being more communicative. We should have ALL had consistent – maybe even written instructions and have more information about the model, age, etc. Perhaps some instructions on the door.
- Silicone models were unrealistic and a waste of time.
- Silicone breast models were beneficial for me. They give you a sense of how hard you need to look and how thorough you need to exam the breast. I would have liked some immediate feedback on those.
- The only negative I have is that it [the course] should be done sooner. It should be in medical school and re-iterated every year.

10. SUGGESTIONS FOR IMPROVING

ST LAWRENCE/SPARROW 10

- I didn't like doing the breast exam on the same person 3 times in a row; I felt like I lost interest.
- I don't know how much I really got out of that; I wouldn't have care if I had the same model twice if they would have had an abnormality. Or even one normal, two abnormal.
- Smaller groups; assistance in finding abnormalities on silicone models.
- Feedback on silicone models exam.... I still don't know how I did!
- Session was very long.
- Add a mid-way review, in 6 months, to see if people were using the techniques learned
- Ditto. Review every 6 months. Beneficial for me because I didn't feel comfortable with breast exams.
- Whole day was beneficial!
- Session on Gail model could have been shorter!
- Great experience. Am using the knowledge I learned. My whole perspective is different now.
- A comfortable way in to the seated exam to teach us some skills about what would make that seated exam more comfortable... how you introduce that: how you talk to the patient about that and use that as an educated process
- Immediate feedback on the how we did on the silicone breast model exam. Did we find them all? What did we miss? How did we miss it? Know what a soft one feels like, know/feel what is meant by ½ centimeter.... instead of us just writing it down and not knowing.
- Clinical scenarios would be a very good idea. That's what we need to do is take these factoids and assimilate and be able to do patient care with.
- I appreciated the live model feedback. That was very helpful. I also think the silicone model test might have been introduced differently. The whole goal as far as what we thought was to try to find each one and therefore we didn't concentrate on practicing our technique and improving it.
- Silicone breast models was way too much and way too many.
- Wish there was more emphasis placed on aspirations. We didn't get a lot of that.
- Appreciated the pink sheet and the charts. I thought the feedback from the live models was excellent. I liked the breadth of material that we got. While I probably didn't use it as much as I'd like to have, it's nice to know that it's there and that I have a condensed source to check with.
- I would have liked to have seen some follow up from the test and the silicone models.
- One change that I recommend is that while we're doing one or two silicone models, have someone right there with you watching your exam to give further feedback.
- Clinical scenarios from models are best teacher. Having breast problems and patients that are used to teaching is what is really going to get the point across.
- It is a real benefit to have MSU research involved.

MIDLAND 10

- 1 or 2 more workshops per year;
- more data in the package
- Change the lecture portion: 3 to 4 hours was tedious. Attention span after first ½ hour really drifts. - maybe break up the lectures with interspersed stations.
- I agree. It got tedious quickly. If this thing is split up over 2 days – maybe come back a week or several days later to review/revisit – would solidify info in my mind, rather than this huge infusion of information and then “boom” you're done.

- ***SUGGESTION FROM MODERATOR: One of the follow ups might be of actual cases presented, either of a difficult situation or of a follow up decision.***
- Time factor – do quicker. **WOULD LIKE TO HAVE GAIL MODELS AVAILABLE.**
- I don't remember hearing what was the evidence for having patients sit up? What is the support for doing this?
- Practice with models made a difference
- 2 hours more with models
- more live experiences
- more clinical skills.
- The exam process made an impact on me and some of the data that was pointed out stuck with me. I haven't looked at any of the material. I thought there was a lot of material presented. I few things stuck out, but MORE things could have stuck out. If high points were emphasized, there could have been a condensation. The algorithms I found to be useful.
- More evidence based. I like information precise with reinforcement with pearls. [*of wisdom, we presume*]
- The clinical hands-on part was the part I liked most. The breast exams. I found that very very helpful. I also found the algorithms helpful insofar as they elucidated what I do need to do if I do run into a quest.
- There was such a volume of information in the beginning. Though I thought all of it was tintillating (sic), you think about how interesting all that information would be [*ed: group laughter drowns out the rest of the sentence.*]
- I thought it was good information although there was a LOT of information – sensory overload.
- There was too much information. It was overwhelming. You need to have 10 key points or goals to accomplish it and realize that everything else you throw in there is just going to burn people out and divert them away from whatever key points you want to come across. If you try to accomplish everything in one fell swoop, the important stuff gets lost.
- If your goal is to improve practitioner practice, you need to set it for the audience. Maybe a reinforcement of the 10 key points about 6 months later.
- If you had 10 key points with evidence-based information to support them, that would ultimately change our practice with our breast care and be much more effective than all the different little facts that were given.

SAGINAW 10

- It's always good to have a repeat/review.
- Didn't use technique on everyone; didn't feel motivation
- Artificial [silicone] breasts were very difficult to palpate
- With regard to the training, a lot of times when you get introduced to something when you first start out you can only remember so many things so you pick out so many things. The next time you hear it, you've done some things and you get a different message and you add new points to your training, so that's the advantage to repeating it.
- The course was maybe a little too much with all the paperwork and forms. I understand it was quite a research, but for the most part, I think, again, with having an MSU background, there were no earth-shattering revelations or "Wow, I didn't know that," or Boy, I'm sure happy I learned that."
- At MSU, Janet taught us, and we even had the same models in medical school.

- Well, it's been a while since I've been at MSU so I didn't recognize the models, but my comment would be to have less didactic, more models, and even some models with abnormalities would have been very valuable.
- The silicone models are not really very helpful because the skin doesn't feel like the skin on the models. If we can perhaps work with something that feels a little more real, it would be beneficial.
- You won't use the technique on silicone models that you use on your patients.
- For me it was excellent
- Even though most everybody had negative comments on the **silicone models**, all of which is true, I think the **positive aspect of it is that it did remind us to record the size of the nodule, its depth, its firmness so that when we do a real breast we're all doing the same thing.**
- I want to interject. Those plastic models, the depth is kind of questionable. I want a more clear definition about what you call "deep."
- Attitude questions should have had more options rather than just "agree," "strongly agree" and "disagree."
- More case scenarios
- Different kinds of exams
- The consent forms say "voluntary."⁴ We were told our participation was mandatory.
- Change the consent forms

SPARROW/ST. LAWRENCE 10 [Feedback largely incorporated into #8 and #9]

KALAMAZOO 10

- Silicone models, interesting, but not real.
- Day was too long. The time with the [live] models could have been shortened.
- Silicone models were not helpful.
- Silicone models made me more vigilant.
- I didn't remember a lot of the didactics. Too long.
- Too much time spent on silicone models.
- The day was incredibly long and painful.

Group II

- It's been a year... I'm trying to remember the curriculum. I do remember the didactic was very informative. Honestly, when I was taking the test [today] I couldn't remember anything because I just haven't thought about it in that much detail since last year.
- The model I had a year ago was OK. The one I had today was really informative. She said, You need to do this, this, this and this. But I had a much shyer model last year so it really wasn't very educational.
- I think the silicone breasts are helpful ... not at all like a real breast but will give you some practice in estimating size and things like that. Worthwhile.
- It was really, really long.
- The model exam was OK. But the little silicone ones don't feel anything like a real breast. And it's kind of like a game so it's fun, but nothing realistic because my hand hurt and my hand never hurt after examining a patient. I felt maybe two breast masses in my life that turned out to be cancer. The first one I felt wasn't that impressive. The last one I felt was like a rock-hard BB. You just need experience feeling real ones.
- The silicone models – I don't want to say they're a joke – but I really think they were so different from normal breast tissue that I'm not entirely sure of the value of using them. But since you're

not going to go out and find a bunch of women with breast masses, I respect the need for some system for trying to teach us what it feels like.

- I don't remember a thing from the didactic sessions. I can't remember didactic sessions from 1 month ago, let alone a year ago. A lot of the test questions, if you know them, that's great, but I don't know how many of them really affect my ability to provide quality care.
- From the clinical standpoint, the most important things are, 1) what do you need to do, 2) why do you need to do it and 3) what do you need to tell the patient. We don't have an hour to talk to the patient so if they ask me why I'm doing something I should be able to tell them. I don't have the numbers on the tip of my tongue and those [numbers and risk factors] would be things that would be good to reinforce. I think a 10-minute session of the really important key points would be better than 2+ hours of something I'll forget in a year. Or even a reminder card for us, or for the patients to put on their shower., e.g.: "We're doing a breast exam this way because 1 in 8 of you will have a breast cancer before you die;" or, "You're doing it this week because you had a period last week." etc. etc.
- One other thing that would be neat would be to get feedback – not just feedback on how I did, but key points that you want us to take with us and points that are reinforced.

Transcribed by M.R. Struck
Summer 2000
(rev.8/30/00)

APPENDIX 24

REPORTABLE OUTCOMES

**Abstracts and Poster Presentations,
Masters's Thesis,
Summary of the Grant
to Train Nurse Practitioners**

Abstracts and Poster Presentations



CLINICAL BREAST EXAMINATION, CAN WE BE MORE SPECIFIC?

MR Brennan*, HC Barry, DR Pathak, JR Osuch and PK Pathak (Department of Epidemiology, College of Human Medicine, Michigan State University, East Lansing, MI 48823)

In academic medicine a physician's sensitivity and specificity of lump detection for a clinical breast exam (CBE) is assessed based on the examination of silicone breast models with a known number and location of lumps. While we agree with the definition of sensitivity, we believe it is possible to have an improved approach to calculate specificity. The current definition of specificity used to test a physician's CBE skills is, one minus the quotient of the number of silicone breasts with at least one false positive detected divided by the total number of silicone breasts used in the assessment. With this method of calculating specificity, when two physicians examine the same silicone breast, a physician who marks one false positive is equally penalized as a physician who marks an infinite number of false positives. Therefore it is difficult to discern varying levels of specificity amongst tested clinicians. We believe the reason for this less accurate measurement of specificity is due to the unit of analysis in the numerator and denominator being the entire breast. We developed computer simulations to address this dilemma. Computer simulations were performed using an Excel spreadsheet. Simulations using three units of analysis were performed, one using the current method, the second using quartiles of the breast, and the third using the thirty-six cells that comprised the simulated breast. These simulations were examined for differences in the calculated specificity. By developing a more precise methodology, a better way to quantify the CBE skills of the clinician may be identified.

Abstract ID#: 2054

Password: 793503

ACCEPTED

Final Paper Number: 827

Guarantor: Michael R. Brennan

Category Selection: Poster Session III (P)

Preferred Presentation Format: Poster

Institution: Department of Epidemiology, College of Human Medicine, Michigan State University, East Lansing, MI, 48823 USA

Keywords: Cancer, Methods, Women's Health

Student presenter

First Author



BREAST CANCER SCREENING IN THREE MICHIGAN FAMILY PRACTICE CLINICS

S Huang*, J Osuch, B Given, HC Barry, J Holtrop, M Swanson and D Pathak (Michigan State University, East Lansing, MI 48823)

As part of a research project supported by the Department of Defense* on training physicians for proper follow-up of breast abnormalities, we calculated the breast cancer (BC) screening rate for women 40-70 years old in three Michigan Family Practice Clinics (FPC) between 5/1/98 and 7/31/99. Breast care related office visits and phone calls for all eligible women in the clinics were abstracted. Symptomatic women were eliminated from the calculation. The screening rates for CBE alone were 56.5%, 50.3%, and 27%. Only 0.5-2% of women who had CBE recommended refused the examination. The rates for mammography were 55.4%, 36.0%, and 28%. The refusal rates for recommended mammography were 0.8-2% and 94% of women had mammogram done within 3 months of recommendation. The percentages of women who had both CBE and mammography were 39.1%, 25.9%, and 16.7%. Among them, 90% had both tests done within 3 months. For women ≥ 50 , the mammography screening rates were consistently higher than for women < 50 , for all three clinics. CBE screening rates varied between the two age groups. Women ≥ 50 had higher, equal, and lower rates at clinic 1, 2 and 3, respectively, compared to women < 50 . These results underline two important points: (1) the current BC screening rates for CBE and mammography individually or combined are unacceptably low (2) when screening is recommended, compliance with the recommendation is above 98% and accomplished 90% of the time within 3 months. To meet the Healthy People 2000 recommended mammography and CBE combined screening rate of 60%, interventions to improve these findings at FPC will be urgently needed.

*DAMD17-98-1-8318

Abstract ID#: 1262

Password: 333788

ACCEPTED

Final Paper Number: 390

Guarantor: Suiying Huang

Category Selection: Poster Session II (P)

Preferred Presentation Format: Poster

Institution: Michigan State University, East Lansing, MI, 48823 USA

Keywords: Cancer, Screening, Women's Health

Student presenter

Abstract

Introduction: To address the inconsistency of training in clinical breast examination (CBE) among graduates of medical schools and residents, we developed and implemented a training intervention. This paper presents the immediate effect of the initial phase of the intervention on knowledge, CBE technique, and CBE sensitivity and specificity of breast lump detection.

Methods: We randomized 8 family practice residents into control and intervention groups. The intervention was a 1-day training session composed of didactic, interactive, and skills components. The control group received no training. We assessed knowledge, attitudes, and beliefs about breast cancer screening, risk factors for breast cancer, and follow-up for abnormalities. CBE technique was assessed using a checklist of 15 components of CBE technique. We used a 30% sensitivity and 70% specificity for technique evaluation and silicone models for lump detection.

Results: 122 physicians, 5 physician assistants, and 2 nurse practitioners participated in one-day workshops in July 1999. The proportion of correct answers to the 15 knowledge questions changed from 33% to 53% ($p < 0.001$). The proportion of correct answers to the 15 CBE technique questions changed from 33% to 71% after the training ($p < 0.001$). The mean percent of the total area inspected during CBE increased from 10% to 20% ($p < 0.001$). The sensitivity for location of the breast lump, defined as the proportion of 15 lumps correctly detected (within 2 cm radius), increased from 64% at baseline to 71% after the training ($p < 0.001$). The sensitivity for location of the breast lump without a false-positive rose from 28% before to 42% after the training.

Discussion: CBE is an important and often poorly performed component of a comprehensive approach to breast cancer detection. This study shows that a comprehensive approach to training was effective in improving knowledge, attitudes, and beliefs about breast cancer screening, and specificity of CBE, which should translate to improved detection of breast cancer. We will re-test participants after 12 months to determine their retention of knowledge and CBE skills gained during the training.

Objectives

To determine the effect of a three component intervention on rates of CBE and mammography, documentation of findings, and timeliness and appropriateness of follow-up of abnormal findings;

- 1) Educational Session (ES)
- 2) Clinical Skills Course (CSC)
- 3) Chart Reminder/Guideline System (CRGS)

To determine the immediate effect of:

- 1) ES on knowledge, attitudes and beliefs (KAB) about breast cancer screening, early detection and follow-up of abnormalities detected as measured by KAB physician survey
- 2) CSC on the competence with which family practice physicians and residents perform CBE as evaluated by patient instructors
- 3) CSC on sensitivity and specificity of lump detection in silicone breast models

TEACHING CLINICAL BREAST EXAMINATION: PRE-POST TRAINING EVALUATION

Dorothy R. Petruc, PhD, Janet R. Osach, MD, Tom Zuber, MD, Jodi Holbrook, PhD, Barbara Green, PhD, G. Marie Swenson, PhD, J. M. Thompson, MD
Department of Family Practice, Michigan State University, Michigan 48824 (313/533-0772)

Methods

Training of resident instructors

- Brief orientation to the project and its goals
- Completion of CBE and health history to determine the patient model had no existing breast health problems or condition
- Instruction and demonstration of proper CBE technique and components
- Instruction on CBE evaluation form including what the component means and how to properly complete the form

Instructions during Educational Session

- Anatomy and physiology
- Epidemiology, genetics, risk factor counseling and Termination
- Breast cancer screening and evidence based medicine
- Breast pain and work-up of occult mammographic abnormalities
- Work-up of abnormal findings on CBE
- Risk management

Instructions during Clinical Skills Course

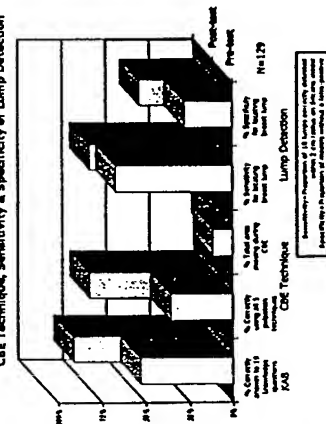
- CBE training using the Breast Examination Teaching Model (BETM) developed by Pennepacker
- Participants taught the six components of the CBE technique performed
- Reinforcement of CBE training using the California Department of Health Services Instructional Video made with Janet Osach, M.D. as a consultant
- Teaching lump detection in silicone breast models with lumps of varying size (3-10mm in diameter), hardness and mobility

Statistical approach

To assess the impact of the ES and CSC on various outcome measures of interest a paired t-test was used initially. Since the workshops were offered at 5 different sites, to adjust for the possible effect of site, analysis of covariance was also used (ANCOVA) with indicator variables for the various sites included in the model. No significant differences were observed between the sites for the effect of intervention on improvement in knowledge, CBE technique, and sensitivity. Therefore, results of paired t-tests are reported for these outcome measures. For specificity, a significant difference in the level of improvement was observed between the sites. Although we provide the overall average level of improvement in specificity, site specific improvements will be reported in the final manuscript.

Results

Pre-Post Training Evaluation about KAB, Competence of CBE Technique, Sensitivity & Specificity of Lump Detection



Evaluation of Physician Workshop (N=129)



Discussion & Conclusions

We have successfully completed the training, assessed baseline and post-training cognitive and clinical skills. We have implemented the charts reminder system for the intervention sites. The charts audits for baseline year are complete. The analysis of immediate effect of the training session found that in the short term the curriculum significantly improved:

- 1) Knowledge and management of breast cancer related issues
- 2) CBE technique
- 3) Sensitivity and specificity of breast lump detection

Assessment of the long term effect of the curriculum is currently being conducted. The curriculum will be provided to the control sites in August and September 2000.

One unexpected outcome is that we have been asked to provide this curriculum to other health care professionals (Nurse Practitioners, Ob/Gyn residents, etc.).

Tasks completed:

- ✓ **Task 1:** Develop, pilot test and refine chart audit and fact/documentation forms
- ✓ **Task 2:** Develop materials on risk management principles and guidelines for follow-up of abnormal findings for the Educational Session Course pack
- ✓ **Task 3:** Preparation of residency sites: A list of female patients 40-70 years old; Randomize sites to Intervention and Control arms
- ✓ **Task 4:** Assemble Chart Reminder/Guideline Kits for the intervention sites
- ✓ **Task 5:** 2-day nurse abstractors training workshop; Distribute to nurse abstractors chart audit forms and chart reminder guideline system (CRGS)
- ✓ **Task 6:** Develop data management system for chart audit data
- ✓ **Task 7:** Hire and train patient instructors in evaluation of clinical breast examination (CBE) techniques
- ✓ **Task 8:** Workshop on "Screening and diagnosis of Breast Cancer for Primary Care Physician"; 1) KAB survey to collect baseline data on breast cancer screening and early diagnosis; 2) Collect baseline data on skills in CBE performance; 3) Conduct 1-day ES & CSC workshop; 4) Repeat all measurements from the pre-test at the end of the workshop
- ✓ **Task 9:** Data entry and analysis of data collected at time of intervention: 1) Pre-post outcome measures on KAB
- ✓ **Task 10:** Pre-post outcome measures on CBE skills
- ✓ **Task 11:** Baseline chart audit (8/98 - 7/99): 1) An ACCESS database was created for data entry and placed on laptop computers; 2) Nurse abstractors at each site were trained to enter data on computer and to use FTP for data transmission
- ✓ **Task 12:** Quality control audit process
- ✓ **Task 13:** Data entry and analysis of baseline chart audit
- ✓ **Task 14:** Data analysis of baseline outcome measures

Tasks to be completed:

- ✓ **Task 15:** Data entry and analysis of KAB and CBE data collected for the evaluation of training retention; compare data from Task 16 to data from Task 8
- ✓ **Task 16:** Assess implementation of CRGS: 1) Convene focus groups at each site; 2) Identify local/global implementation issues; 3) Compare and contrast themes across sites
- ✓ **Task 17:** Hire and train nurse auditors for the post-intervention chart audit
- ✓ **Task 18:** Post-intervention chart audit (8/99-7/00)
- ✓ **Task 19:** Quality control of post-intervention chart audit at each site
- ✓ **Task 20:** Data entry and analysis of the post-intervention chart audit
- ✓ **Task 21:** Manuscript preparation and dissemination

ABSTRACT

**TEACHING CLINICAL BREAST EXAMINATION: PRE-POST TRAINING
EVALUATION**

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Introduction: Training in Clinical Breast Examination (CBE) is inconsistent among graduates of medical schools and residencies. To address this inconsistency, we developed a standard-based approach to breast cancer screening and management of abnormal findings. This paper presents the immediate effect of the initial phase of the intervention on knowledge, CBE technique and CBE sensitivity and specificity of breast lump detection.

Methods: We randomized eight family practice residencies into control and intervention groups. The intervention was a one-day training session composed of didactic, interactive and skills workshops. Comprehensive manual on breast care was provided. Before, and immediately after the training, we assessed: 1) knowledge, attitudes, and beliefs about breast cancer screening, risk factors for breast cancer, and follow-up for abnormalities; 2) CBE technique; 3) CBE sensitivity and specificity for lump detection. The skill workshops used patient instructors for technique evaluation and silicone models for lump detection.

Results: One hundred twenty two physicians, five physician assistants and two nurse practitioners participated in one-day workshops in July 1999. The proportion of correct answers to the 19 knowledge questions changed from a mean of 53% (range 12% to 86%) before to 80% (range 50% to 98%) after the training ($p < 0.001$). The proportion of physicians correctly using all five components of palpation technique rose from 36% to 71% after the training ($p < 0.001$). The mean percent of the total area missed during CBE decreased from 11.4% (range 0% to 72%) before to 1.1% (range 0% to 41%) after the training ($p < 0.001$). The sensitivity for location of the breast lump, defined as the proportion of 18 lumps correctly detected (within 2 cm radius), increased from 67% at baseline to 71% after the training ($p < 0.05$). The specificity, defined as percent of models without a false-positive, rose from 28% before to 42% after the training.

Discussion: CBE is an important and often poorly performed component of a comprehensive approach to breast cancer detection. This study shows that a comprehensive approach to training was effective in improving short-term knowledge, technique, sensitivity and specificity of CBE, which should translate to improved detection of breast cancer. We will re-test participants after 12 months to determine their retention of knowledge and CBE skills gained during the training.

The U.S. Army Medical Research and Materiel Command under DAMD17-98-1-8318 supported this work.

Masters's Thesis

Breast Cancer Screening in Three Michigan
Family Practice Clinics

By

Suiying Huang

A THESIS

Submitted to
Michigan State University
in partial fulfillment of the requirements
for the degree of

MASTER OF SCIENCE

Department of Epidemiology

2001

ABSTRACT

BREAST CANCER SCREENING IN THREE MICHIGAN FAMILY PRACTICE CLINICS

By

Suiying Huang

As part of a research project supported by the Department of Defense on training physicians for proper follow-up of breast abnormalities, we calculated the breast cancer (BC) screening rate for women 40-70 years old in three Michigan Family Practice Clinics (FPC) between 5/1/98 and 7/31/99. Breast care related office visits and phone calls for all eligible women in the clinics were abstracted. Symptomatic women were eliminated from the calculation. The screening rates for CBE performed alone were 56.5%, 50.3%, and 27%. The rates for mammography were 55.4%, 36.0%, and 28%, and 94% of women had the mammogram done within 3 months of recommendation. The percentages of women who had both CBE and mammography were 35.8%, 22.8%, and 16.7%. Among them, 90% had both tests done within 3 months. For women ≥ 50 , the mammography screening rates were consistently higher than for women < 50 , for all three clinics. CBE screening rates varied between the two age groups. These results underline two important points: (1) the current BC screening rates for CBE and mammography individually or combined are unacceptably low (2) when screening is recommended, it is accomplished 90% of the time within 3 months. To meet the Healthy People 2000 recommended mammography and CBE combined screening rate of 60%, interventions to improve these findings at FPC will be urgently needed.

To Mom and Dad

ACKNOWLEDGEMENTS

I would like to thank my thesis advisor Dr. Dorothy Pathak for her continuous guidance and support. I am also indebted to Dr. Janet Osuch, a highly respected breast surgeon. It is unlikely that we would have achieved much of what we did without her insightful suggestions and expertise in the breast cancer field. I believe she was correct in saying "Suiying owes me big". I would additionally like to thank Dr. Ellen Velie for her time and stimulating discussions. The last two years that I worked on the DOD project had been both a rewarding and educational experience. I would like to thank all the members on this project, with special acknowledgement of Dr. Jodi Holtrop, Dr. Barbara Givens, Maria Struck, and all the nurses who abstracted medical charts for us. I would like to extend a special thanks to Dr. Jianping He, for all that she has taught me during these two years. I would further like to thank Dr. Wilfred Karmaus for his guidance, as well as all the team members in the Fisheaters project. It has been great fun working with all of you, and I thank everyone for your patience with me. Last, but not the least, I would like to thank my parents for their endless love and support.

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LIST OF ABBREVIATIONS

BC - Breast Cancer

CBE - Clinical Breast Exam

ACS - American Cancer Society

CHAPTER 1 INTRODUCTION

Breast cancer (BC) is the most common cancer among women, and it is the second leading cause of cancer death in women, next to lung cancer. The American Cancer Society (ACS) estimated that there will be 182,800 new cases of invasive BC among women and about 40,800 deaths in the United States during 2000 [1]. Based on current incidence rates, ACS estimates that one out of every nine women in the United States will develop BC at some time during her life.

One effective strategy in reducing mortality from cancer is early detection by screening. Early detection of cancer can result in treatment before the tumor metastasizes and can lead to reduction in mortality from the disease. For a screening test to be effective, that test must be capable of diagnosing disease prior to it becoming symptomatic [2].

The main screening methods for BC have been mammography and clinical breast examination (CBE) performed by trained health professionals. Mammography can generally detect smaller tumors than those found by CBE (1.5cm versus 1.8cm) [3].

Recommendations for screening in normal-risk women in the US vary by cancer research organizations. Every major professional cancer organization

recommends screening in women 50-69 at intervals of 1-2 years [3].

Recommendations are inconsistent for women aged 40-49 and 70 and over. The American Cancer Society and the American College of Radiology recommend annual mammography and CBE for women 40 to 49 years, while the National Cancer Institute (NCI) recommends screening mammography every 1 to 2 years for women of the same age group [3] [4]. All of these recommendations apply only to asymptomatic women. The frequency and type of examination for symptomatic and high-risk women will vary individually and should be determined by the responsible physician.

Further, it is recognized that in order to eliminate the false negative rates of either CBE or mammography alone, the two tests should be done as close in time as possible [5]. Hicks et al found that the individual sensitivities of mammography and CBE for detecting BC were 62% and 24%, respectively. However the sensitivity of the two methods combined was 75% [5].

Historically, CBE has been a neglected part of the annual physical examination. Many physicians attribute this to lack of adequate training of CBE in medical school and also to the unrealistic amount of time that is required for doing a proper exam [6]. In addition, several investigators have recently reported that as the use of mammography increases, CBE usage has decreased [3] [7] [8].

I. Breast Cancer Screening Evaluation

A. Efficacy of screening

Efficacy, as defined by Last, is the extent to which a specific intervention produces a beneficial result under ideal conditions [2]. Efficacy of screening can be determined through randomized clinical trials, and there have been several randomized clinical trials testing the value of BC screening (Table 1).

Randomized Trials

The first of these, and the only one conducted in the US, was the Health Insurance Plan of Greater New York (HIP) study, which began in 1963 and ended in 1986. The primary objective of the study was “to determine whether periodic breast cancer screening utilizing mammography and clinical examination holds substantial promise for a long-term reduction in mortality from breast cancer in the female population” [9] [10]. Women aged 40-64 years were enrolled and were randomized individually. The screened group numbered 30,131, compared to a control group of 30,565. Each woman in the intervention group was invited for an initial mammogram and three 12-month interval two-view follow-up mammograms, plus clinical examinations. Women in the control group followed their usual patterns of care. After 10 years, the cumulative mortality from BC was reduced 29% (RR = 0.71, CI 0.55 – 0.92) in the study group compared to the control group. However, the reduction in mortality differed by woman’s age of entry to the study. For women younger than 50 years, the RR

was 0.81 (CI 0.53 – 1.24). Among women older than 50 years, the RR was 0.65 (CI 0.46 – 0.92).

Two randomized mammography screening trials were initiated in Sweden in the mid-1970's. The Malmö trial was initiated in 1976. Women enrolled were aged 45-69 years. Subjects were randomized for an 18-24 months interval, one-view, mammographic screening as part of their usual medical care. Women in the control group did not receive screening. After 9 years of follow-up, the RR for all women in the screened group was 0.96 (CI 0.68 – 1.35). Among women aged 50 years and older at entry, the RR was 0.79 (CI 0.51 – 1.24). Among women aged less than 50 years at entry, the RR was 1.29 (CI 0.74 – 2.25). However, in an analysis done in women 40-49 after 12 years of follow-up, the RR became 0.64 (CI 0.45 – 0.89) [11]. The results showed that mammographic screening may lead to reduced mortality from BC after long-term follow-up.

In 1977, the Swedish National Board of Health and Welfare started another randomized controlled trial in two counties (Kopparberg and Östergötland counties) to determine the effect of screening with a 24-33 month interval, one-view, mammogram on reducing mortality from BC [12]. Women in the control group followed their usual patterns of care. With an average of 13 years of follow-up, the cumulative mortality from breast cancer was 30% lower in the study group than it was in the control group (RR = 0.7, CI 0.55 – 0.87). The effect of screening was almost entirely concentrated among older women. In

Kopparberg county, the RR was 0.73 (CI 0.31 – 1.4) in women < 50 years, and 0.58 (CI 0.43 – 0.78) in women older than 50. In Ostergotland county, among women < 50 years old, the RR was 1.02 (CI 0.52 – 1.99), and for women 50 years and older, the RR was 0.73 (CI 0.56 – 0.97).

In another randomized clinical trial conducted in Edinburgh, 46,000 women aged 45-64 years were recruited during the period of 1978-1981. The screening methods included an annual two-view mammogram and CBE. Women in the control group received routine health care. After 7 years of follow-up, a non-significant mortality reduction was observed among women < 50 years of age at entry (RR = 0.98, CI 0.45 – 2.1). Among women \geq 50 years at entry, the RR was 0.80 (CI 0.54 – 1.17) [13]. In an analysis performed in women less than 50 after 12 years of follow-up, there was a non-significant mortality reduction of 15% (RR = 0.85, CI 0.55 – 1.41) [14].

Another Swedish trial, the Stockholm trial, was initiated in 1981 [17] [18]. The number of women aged 40 to 64 in the intervention arm was 40,000, while the number in the control group was 20,000. The screening method used was a one-view, 28-month interval mammography. Women in the control group did not receive screening. After follow-up of 11.4 years, a non-significant 26% mortality reduction was observed in all women in the intervention group (RR = 0.74, CI 0.5 – 1.1). Beneficial effects were observed in women older than 50 years (RR =

0.62, CI 0.38 – 1.0). For women aged 40-49 years, no effect on mortality was found (RR = 1.08, CI 0.5 – 1.7).

The Canadian National Breast Screening study enrolled 90,000 women 40-59 years of age, starting from 1981. These women were randomly distributed into an intervention group receiving both annual two-view mammography and CBE or into a control group receiving only annual CBE [15, 16]. After 10.5 years of follow-up, among those women aged younger than 50 at entry, the RR of mortality from BC for those in the intervention group was 1.14 (CI 0.83 – 1.56), compared to controls. Among women aged 50 years and above, the RR was 0.97 (CI 0.62 – 1.52). Their results showed that screening with yearly two-view mammography and CBE had no impact on the rate of death from breast cancer for up to 10 years of follow-up from entry in this trial.

The Gothenburg breast cancer screening trial started in 1982 in Sweden. The trial randomized 52,000 women aged 40 - 64 into two groups: one received mammographic screening every 18 months, and one control group, who was not invited to screening until the fifth screen of the intervention group [19] [20]. After 7 years of follow-up, no significant reduction in mortality in all women in the screened group was observed. However, after 12 years, there was a significant 44% reduction in mortality from BC in the screened group of women < 50 years at entry compared to the control group (RR = 0.56, CI 0.32 – 0.98) Their data

suggested that at least 10-12 years of follow-up is needed for the reduction in mortality to be seen among women under the age of 50.

Meta-analysis

Hendrick et al conducted a meta-analysis of eight randomized controlled trials of screening mammography involving women aged 40-49 at entry [21]. The average follow-up time was 12.7 years. The meta-analysis was performed using a Mantel-Haenszel estimator method. After combining the most recent follow-up data, a statistically significant 18% mortality reduction among women who were randomized to screening mammography was observed (RR = 0.82, CI 0.71 – 0.95). This meta-analysis showed, by combining all eight randomized clinical trials involving women younger than 50 years at entry, a statistically significant mortality reduction due to regular screening mammography was observed. This analysis overcame many of the power limitations in the younger age groups that challenged the accuracy of the previous trials, due to the lower prevalence of BC in this age group.

B. Effectiveness of screening

Effectiveness, as defined by Last, is a measurement of the extent to which a specific intervention, when deployed in the field in routine circumstances, does what it is intended to do for a specified population [2].

One of the largest tests of BC screening effectiveness was the Breast Cancer Detection Demonstration Project (BCDDP), sponsored by the American Cancer Society and the National Cancer Institute. Between 1973 and 1981, a total of 283,222 women aged 35-74 years participated in the BCDDP program. The program provided annual two-view screening mammography and CBE for five years, in 29 centers throughout the US. This project was a screening demonstration project that did not include a comparison group of women who did not receive mammographic screening, and so could not measure mortality reduction. However, after 20 years of follow-up, results showed that 50-59% of the cancers diagnosed were stage 0 or I [22]. The results demonstrated that BC can be detected at an earlier stage among women of all ages when screening modalities are used.

A second large-scale non-randomized trial was initiated in the United Kingdom in 1979 to evaluate the effectiveness of mammography and CBE in women aged 45 to 64 years. Subjects were not individually randomized and instead screening eligibility depended on their area of residence. Women in the screened population (n=45,841) were offered annual physical exam and biennial mammography for 7 years. Women in the control population (n = 127,117) were not offered screening services. After 16 years of follow-up, breast cancer mortality was 27% lower in the study group, compared to the control group (RR = 0.73, CI 0.63 – 0.84) [23]. There was no evidence of less benefit in women aged 45-46 years at entry, the effect of screening in this age group begins to emerge

after 3-4 years. After 16 years, a 30% (RR = 0.7, CI 0.57 – 0.86) reduction is seen in women aged 45-46 years at entry. However, this trial is subject to criticism since it is not individually randomized. Possible confounding factors, such as inherent risk across the counties and differences in social-economic status, should be considered when interpreting the results.

C. Efficiency of screening

In addition to efficacy and effectiveness, BC screening efficiencies must also be considered. Efficiency, as defined by Last, is the effects or end results achieved in relation to the effort expended in terms of money, resources, and time [2].

Cost

The cost of screening is usually measured by the cost per year of life saved. In 1995, it was estimated that cost/year of life saved by screening mammography ranged from \$6,000 - \$13,000, with a median of \$8,900 [24]. In comparison, the median cost per year of life saved in the appropriate age groups for other interventions were: \$6,000 for cholesterol, \$12,000 for cervical cancer, and \$42,000 for hormone replacement therapy. This demonstrated that annual mammography compares favorably with other public health interventions.

Risks

However, there are existing potential hazards associated with BC screening as well, especially with mammographic screening [25]. First, if earlier

time of diagnosis doesn't translate into a reduction in breast cancer mortality for an individual woman, then some women are given advanced notice of a cancer diagnosis without tangible gain [26]. This can, of course, have an adverse effect on the quality of life. Second, mammographic screening results in exposure to low-dose radiation, and this may induce breast cancer, especially for women with the inherited gene for ataxia-telangiectasia [3]. Third, false positive results can lead to unnecessary breast biopsies and anxiety [26]. These patients have to face the financial/emotional burden of being falsely identified as a potential cancer patient. Finally, mammography has a false negative rate in screening settings of 10-15% [26]. This can lead to false reassurance that cancer is absent and mislead women and their providers.

D. Summary

Despite the potential risks involved, data from clinical trials support on average a 30% mortality reduction in BC resulting from annual or bi-annual mammography and CBE among asymptomatic women between the ages of 50 and 69 years [27]. A meta-analysis of the randomized trials demonstrated a 18% reduction in BC mortality from mammography screening among asymptomatic women between the ages of 40 and 49 years. The lower mortality reduction demonstrated in women 40-49 as compared with women 50 and over is likely due to lack of power to demonstrate a difference based on low prevalence of BC in this age group, the need for longer follow-up time, and the demonstrated need

for shorter screening intervals in younger women, due to shorter cancer sojourn times in this population [28].

Table 1: Summary of Randomized Clinical Trials Testing the Effectiveness of Screening

Location	Time period	Age	# in study group	# in control group	Yrs of F/U ^P	Types of Screening	Interval (mo)	Relative Risk (95% CI)
USA	1963-1986	40-64	30,131	30,565	10	2 V MM ¹ and CBE	12	<50 0.81 (0.53-1.24) >50 0.65 (0.46-0.92)
	1976-	45-69	21,088	21,195	12	2 V MM ¹	18-24	After 9 years <50 1.29 (0.74-2.25) >50 0.79 (0.51-1.24)
Kopparberg, Sweden	1977-1984	40-74	38,589	18,582	13	1 V MM ²	24	After 12 years <50 0.64 (0.45-0.89) <50 0.73 (0.31-1.4) >50 0.58 (0.43-0.78)
	1977-1984	40-74	38,491	37,403	13	1 V MM ²	24	<50 1.02 (0.52-1.99) >50 0.73 (0.56-0.97)
Edinburgh, UK	1978 - 1985	45-64	23,000	23,000	12	2 V MM ¹ and CBE	12	After 7 years <50 0.98 (0.45-2.1) >50 0.80 (0.54-1.17)
								After 12 years <50 0.85 (0.55-1.41)
Canada	1980	40-49	25,000	25,000	10.5	2 V MM ¹ and CBE	12	1.14 (CI 0.83 – 1.56)
Canada	1980	50-59	20,000	20,000	8.3	2 V MM ¹ and CBE	12	0.97 (CI 0.62 – 1.52)

Location	Time period	Age	# in study group	# in control group	Yrs of F/UP	Types of Screening	Interval (mo)	Relative Risk (95% CI)	
Stockholm, Sweden	1981-1986	40-64	40,000	20,000	11	1 V MM ²	28	<50	1.08 (0.54-1.7)
								>50	0.62 (0.38-1.0)
Gothernburg, Sweden	1982-1994	40-59	22,000	30,000	12	2 V MM ¹	18	After 7 years	
								<50	0.73 (0.3-1.97)
								>50	0.91 (0.5-1.55)
								After 12 years	
								<50	0.56 (0.3-0.98)

1 = 2-view mammography

2 = 1-view mammography

Table 2: Summary of Other Studies Testing the Effectiveness of Screening

Location	Time period	Age	# in study group	# in control group	Yrs of F/UP	Types of Screening	Interval (mo)	Relative Risk (95% CI) Or Other Findings
Meta-analysis		40-49			12.7			0.82 (0.71-0.95)
UK Trial	1979-	45-64	45,841	127,117	16	1 V MM ² and CBE	12	<50 50-54 55-59 60-64 0.7 (0.57-0.86) 0.79 (0.62-1.0) 0.71 (0.56-0.9) 0.7 (0.56-0.92)
BCDDP	1973-1980	35-74	283,222		20	2 V MM ¹ and CBE	12	50-59% of cancer were diagnosed at stage 0 or 1

1 = 2-view mammography

2 = 1-view mammography

II. Current breast cancer screening rates

A. Patient Self-Reported BC Screening Rates

Anderson et al described the use of breast cancer screening within the US population in 1987 and 1992 as reported in the National Health Interview Survey [29]. In 1987, a total of 5,052 women aged 50 years or older were interviewed and asked whether or not they had had mammography and CBE in the past year (Table 3). In 1992, the corresponding women interviewed were 2,709. The percentage of women who self-reported having received a mammogram in 1987 was 16.5%. In 1992, the percentage increased to 35.3%. The percentage of women who self-reported receiving CBE increased from 41.6% in 1987 to 46% in 1992. These figures showed that the usage of BC screening modalities increased between 1987 and 1992 but that levels remained low.

Coleman et al compared annual BC screening rates from a telephone survey conducted in 1988 and again in 1991, among women aged 65 – 74 [8]. Participants were selected from five communities around the country. In 1988, the numbers of women included were 57 in California, 133 in Massachusetts, 124 in North Carolina, 64 in Long Island, and 121 in Philadelphia (Table 3). In 1991, 237 women participated in California, 508 in Massachusetts, 409 in North Carolina, 523 in Long Island, and 479 in Philadelphia. None of the eligible women had a previous history of BC, and all were able to complete the interview or questionnaire. The authors found that mammography use increased from 19-33% in 1988 to 35-59% in 1991. However, among women who received a

mammogram, the percent who also received a CBE decreased from 95% to 85% ($P = 0.001$). They conclude that even though mammography in older women increased dramatically over the 3 years, the use of CBE may be decreasing.

The Centers for Disease Control's 1997 Behavioral Risk Factor Surveillance System (BRFSS) examined the usage of screening mammography, screening CBE, and both examinations among a multistage probability sample of women aged 50 years and older, in 52 states (including the District of Columbia and Puerto Rico) [30]. They used a standard questionnaire to conduct random-digit-dialing telephone surveys. The questionnaire included questions about CBE and mammography. The report was restricted only to screening examinations, which is defined as an examination that was part of a routine check-up. In 1997, the average percentage of women aged 50 years and older who self-reported receiving a screening mammogram in the previous two years was 73.7%; screening CBE 77.0%; and both examinations 66.4% (Table 3).

B. Physician Self-Reported BC Screening Rates

Albanes et al conducted a survey of physicians in Pennsylvania to ascertain current BC early detection practices in 1988 [31]. They found that over 90% of the physicians self-reported having performed annual breast physical examinations in asymptomatic women age 50 years or older (Table 3). However, for this age group, annual mammograms were self-reported as ordered by only 42% of physicians.

Kripalani et al did a survey of self-reported BC screening rates among 700 randomly chosen Texas primary care physicians in 1996, in order to determine their screening behaviors and compliance with national recommendations [32]. For women between 40 and 49 years of age, 75.5% of physicians reported recommending mammography every 1-2 year(s), and 8.4% suggested screening annually (Table 3). For women 50 years and older, 81.4% reported recommending annual mammography and 16.1% of clinicians recommended screening every 1 to 2 years. The authors concluded that the screening practices reported by this sample of Texas physicians compared very favorably with those reported by other authors.

Slanetz et al conducted questionnaires among 278 physicians in the state of Massachusetts concerning their use of BC screening in 1995 [33]. In women aged less than 50, 144 (52%) of 278 physicians self-reported performing annual CBE combined with screening mammography every two years, whereas 57 (21%) favored annual mammography and CBE (Table 3). In women aged 50 years and older, 232 (83%) physicians reported screening patients annually with CBE and mammography.

C. Chart-Audited BC Screening Rates

Burns et al investigated the prevalence of CBE among women receiving mammography [7]. This retrospective cohort consisted of one hundred women aged 50 years or older who received mammography between 1987 and 1990 in Boston, Mass. Chart review recorded demographic information, severity of illness, and performance of CBE, within 1 year to 18 months after the mammography. They found that 76% of the population studied had mammography and CBE, while the remaining 24% had mammography alone. Socioeconomic factors did not differ for women with and without screening examinations. However, female breast care providers were more likely to perform screening examinations (both mammography and CBE) than male providers. The authors concluded that mammography may be replacing CBE, especially among patients receiving breast care from male providers. Interventions that are targeted to male providers should help to improve the use of both CBE and mammography.

Love et al determined the frequency and determinants of mammography screening in 24 nonacademic primary care group practices, during a 3-year period, 1988 through 1991 [34]. They audited the medical records and obtained questionnaire responses from 1819 women older than 50 and from their 98 physicians in the non-metropolitan Midwest. Medical record abstraction indicated that mammography was performed in all 3 years in 16.7% of women, in at least two of 3 years in 49.8% of women, and in at least one of 3 years in 81.7% of women (Table 3). The significant predictors for receiving mammography included

family history of BC, health insurance coverage for mammography, and greater annual household income. The strongest predictor for greater frequency of mammography was the discussion of the procedure by a clinic staff member. The authors concluded that clinic staff initiatives with screening mammography have a large impact on higher rates of mammography performed, and should be a focus of intervention research designed to increase use of screening mammography.

Kinsinger et al conducted a randomized controlled trial with primary care practices to evaluate the improvement of performance rates of BC screening through implementation of office systems in 1992 [35]. Physicians in 20 mostly rural counties in North Carolina were assigned to either an intervention group or a control group. The intervention, focusing on BC screening by mammography and CBE, consisted of a series of activities designed to assist primary care practices in developing and implementing individualized office systems for BC screening. To facilitate the implementation of office system plans in the intervention groups, practices were encouraged to use resources for tracking and prompting (e.g., flow sheets, chart prompts and sticker, etc) and for patient education (e.g., brochures listing recommended preventive care for women over 50 years of age). Medical records of women 50 years and older were randomly chosen for data abstraction, both at baseline year (1992) and follow-up year (1995). The numbers of records abstracted were 2,887 and 2,874 for the two years, respectively (Table 3). The chart audits showed an increase from 39% to

51% in the mention of mammography ("mention" of mammography on the visit note in any way) in the intervention practices, compared with increases from 41% to 44% in the control practices (Odds Ratio = 1.5, CI 1.1 – 2.0). However, there was no significant difference between the two groups in the percent of actual mammograms reported in the charts during the two years. In the intervention group, the percentage of women with a mammogram reported in the chart increased from 28% to 32.7%. In the control group, it increased from 30.6% to 34.0%. Regarding CBE, either completion of CBE or mention of a CBE recommendation was considered. The percentage of women having a CBE either performed or recommended improved from 41.1% to 46.4% in the intervention arm, while it dropped from 44.6% to 43.9% in the control group. The percentages of women whose chart indicated that both mammography and CBE were recommended increased from 28.2% to 38.7% in the intervention group, and 30.3% to 32.6% in the control group. These results showed that outreach interventions to increase rates of BC screening through the development of office systems was modestly successful in improving the documentation of recommendation for mammography, but had little impact on the actual performance of BC screening.

McCarthy et al measured the effect of systemic health care delivery factors and patient demographic factors on the use of mammography among a population of women with insurance coverage for screening mammography in 1992 [36]. They studied 8,805 women, age ≥ 50 years, who were members of a

health maintenance organization in Michigan during 1992. Data were obtained using computerized patient registration and billing systems. In 1992, 47% of the entire study population received a mammogram (Table 3). Not having at least one primary care visit at the time when due for screening was the strongest predictor for not receiving a mammogram. This study suggested that physicians may rely too much on offering mammography during office visits, and that more attention should be focused on a population-based perspective that includes outreach to women who have not visited their health care provider and are overdue for screening. In addition, they also found that the number of visits a patient had was related to obtaining a mammogram. Women who had 2-10 visits had the highest mammography use, compared to those with 1 visit and visits beyond 10.

Tishler et al tried to determine the rates of BC screening for older women cared for in a primary care practice in 1996 [37]. The retrospective cohort consisted of 130 women aged 65 to 80. Data were collected from the hospital's computerized medical record between October 1996 and October 1997. They abstracted all CBE and mammograms performed or recommended during the 2-year study period. They found that among the 130 women, mammography was recommended for 95% of women and completed for 84% (Table 3). CBE was performed on 75% of those women. They reported a very high rate of mammography for women cared for in a hospital-based primary care practice, about twice that reported in most previous studies. The systems in place to

facilitate ordering and tracking of mammograms may have contributed to the unusually high rates of mammography observed. Mammograms were included in a computerized "To Do" list for women aged 50 and older. The clinician received a computer prompt at the time of a patient's visit if it had been more than a year since the women's last mammogram.

D. Comparisons Between Self-report And Chart Audit

Montano et al measured the cancer screening rates of family physicians and compared the measures obtained by physician self-reports, chart audits, and patient surveys in 1988 [38]. Sixty physicians participated in the physician survey, and 326 patients were surveyed for each physician (n = 21,876 patients). Fifty to sixty patients' charts were selected for each participating physician (n = 3,281 patient charts). The chart audit indicated that on average 51% of female patients older than 50 years had had a mammogram within the previous year of the study (between 1988 and 1989), and 57% of women had had a CBE in the past year. Corresponding physicians' self report showed that the rate for mammography was 51% among women aged 50 and older, and 67% for CBE. Patients' self reported survey indicated that 46% of women older than 50 received mammography and 63% received CBE (Table 3).

Whitman et al tried to determine whether chart reviews and patient interviews provide the same information about BC screening [39]. The percentage of women older than 40 who received a breast exam and the

percentage of women older than 50 who received a mammogram at two different public health clinics in Chicago were studied using both chart reviews and telephone interviews. They found that interviews estimated significantly higher proportions of women having received breast exams and mammograms in the previous 12-month interval than were estimated from randomly selected medical records. At center A, the chart review produced an estimate of 6% of women who received CBE, while patient interviews produced an estimate of 55% (Table 3). At center B, the chart review indicated that 36% of the eligible patients had received a CBE in the past year compared to 63% derived from the telephone interview. Regarding mammography, 3% of the eligible patients had mammography recorded in their charts in Center A, while interviews estimated 29%. At Center B, 17% of the women had mammograms recorded in their charts, while interviews produced 38%. This study demonstrated that the BC screening rates in the two clinic centers were low, and there are marked discrepancies between what women report regarding BC screening and what is revealed by reviewing the medical records.

E. Summary of Breast Cancer screening literature review

BC screening rates can be reported by interviewing patients, physicians, or by medical chart auditing. Self-reported BC screening rates are consistently higher than those rates obtained from medical chart auditing. The literature also indicated that since the late 1980's mammography usage had increased steadily. However studies have reported that CBE usage may be decreasing.

Table 3. Literature Review For Breast Cancer Screening Rate

Study	Study Period	Method	N=	Women Age	% CBE done	% Mammogram Done	% Both done
Anderson et al	1987	Women self-report	5052	>= 50	41.6	16.5	
	1992		2709	>= 50	46	35.3	
Coleman et al	1987	Women self-report	499	65-74		19-33%	
	1991		2156	65-74		35-59%	
CDC BRFSS	1996-1997	Women self-report		>= 50	77	73.7	66.4
Albanes et al	1988	Physician self-report	557	>= 50	90	42 (recomm.) ¹	
Slanetz et al	1995	Physician self-report	278	40-49	52	52	52
				>= 50	83	83	83
Kripalani et al	1996	Physician self-report	254	40-49		75.5 (recomm.) ¹	
				>= 50		81.4 (recomm.) ¹	

1 = recommended

Study	Study Period	Method	N=	Women Age	% CBE done	% Mammogram Done	% Both done
Love et al	1988 - 1991	Chart Review	1819	>= 50		16.7 (in all 3 yrs)	
						49.8 (>=2 in 3 yrs)	
						81.7 (>=1 in 3 yrs)	
Kinsinger et al*	1992	Chart Review	2887	>= 50	42.9	29.3	29.3
	1995	Chart Review	2874	>= 50	45.2	33.4	35.7
McCarthy et al	1992	Billing system	8805	>= 50		47	
Tishler et al	1996	Chart Review	130	>= 65	75	84	
Montano et al	1988	Physician Survey	326	>= 50	67	51	
		Patient Survey	11,005	>= 50	63	46	
		Chart Review	3,281	>= 50	57	51	
Whitman et al (Center A)	1989	Chart Review	454	>= 40	6		
			394	>=50		3	
		Phone interview	140	>= 40	55		
			112	>=50		29	
Whitman et al (Center B)	1989	Chart Review	352	>= 40	36		
			144	>=50		17	
		Phone interview	303	>= 40	63		
			115	>=50		38	

* Percentages in the two years were derived from the averages of both intervention and control arms

III. Barriers to screening

Among identified barriers to screening are the discomfort or cost of the procedure, lack of health insurance, lack of transportation or remoteness of the mammography facility [3].

However, the two common reasons women give for not having had a mammogram was that they did not know they needed it and that their physician had not recommended it [40][41]. Fox et al analyzed the reasons provided by 517 women 50 years and older, living in Los Angeles, California, for their underutilization of BC screening [40]. They found that the most important factor that predicted whether a woman ever had a mammogram was whether her physician had talked to her about mammography. Similar results were also found by Grady et al [42]. Their multivariate analyses revealed physician encouragement to be more strongly associated with screening mammography than health status, health care utilization, attitudes, and socio-demographic characteristics. Those women who reported having received a physician recommendation were nearly four times more likely to have ever had a screening mammogram than those not receiving a physician recommendation [42].

These findings further strengthened the critical importance of physician behaviors in the secondary prevention of BC in women.

IV. Overall Study Objective

The current study was conducted to calculate the patient-specific annual screening rates for CBE, mammography, and both, in three Michigan family practice clinics, among women 40-70 years old. For this study, the annual screening rate will be defined as screening occurring during a fifteen-month time frame between 5/1/98 and 7/31/99.

CHAPTER 2 METHOD

I. Data Source:

Data for this analysis were derived from an ongoing large-scale study, funded by the United States Department of Defense. The aim of that study was to enhance primary care physicians' skills in secondary prevention, diagnosis and follow-up of abnormal findings in the control of breast cancer.

II. Study Population:

Three mid-Michigan family practice clinics were included in this analysis. They were designated as sites G, H, and I.

The clinics are members of the Michigan State University Network of Family Practice Residency Programs that serve Michigan by providing family centered care to the citizens of the communities in which they are located. They train resident family physicians to meet primary care needs, and to reach out to the medically underserved and the elderly of these communities. The programs estimated that in 1996 each site saw approximately 10 to 15% of all female patients 40 to 70 years of age. Approximately one-third of the total patients were Medicaid patients.

Each site generated a list of patients who met the following criteria for inclusion in the study:

1. Female
2. Active patients in the practice. This was defined as having at least one visit in the past three years (or since 8/1/96).
3. Between the ages of 40-70 for the baseline year, i.e. born after August 1, 1928 and before July 31, 1959

For each residency program site, two nurses with R.N degrees who were not affiliated with the residency programs were recruited to conduct the audits of the medical records. Each site was provided with one laptop computer in which to enter and transmit data. Nurse abstractor training was held on the campus of Michigan State University. Data entry forms were created in the ACCESS 97 database program and placed on the laptop computers. Sample cases were identified representing a variety of breast care concerns from the Clinical Practice Site at the Michigan State University Family Practice Center and Kalamazoo Center for Medical Studies. Names and all identifiers were blacked-out. Investigators at MSU created the gold standard for the completed audits and each of the practice cases. The nurse auditors abstracted ten sample cases and their entries were reviewed by the investors until the abstractor achieved a Kappa of 90% or higher as a measure of inter-rater agreement. After initial training in August 1999, the auditors were brought back to MSU for an additional

day of training in September, since additional changes were made to the database based on abstractors' feedback. This also allowed the reinforcement of the previously discussed audit guidelines. At the end of the training, each nurse abstractor signed confidentiality agreement forms.

III. Data Collection

The ACCESS database (Appendix 1) captured all patient encounters and phone calls during which breast care activities occurred. Any evidence in the medical record of a mammogram or CBE was recorded, such as a mammogram recommendation or report, comments regarding test refusals and comments regarding the reasons why recommended tests were not performed. We also recorded information regarding screening at outside facilities or by other physicians when documented.

IV. Quality control audit process:

Two trained graduate students in Epidemiology conducted quality assurance audits of the medical records in all three sites. The training manual provided to the nurse abstractors was used as a reference for a one-day training for the students. They were also required to complete the same 10 practice cases as the nurse abstractors. These were reviewed by the investigators as they had been for the nurse abstractors. A 100% Kappa was required from the

graduate students on these cases since they were to serve as the gold standard for the abstractors.

Twelve records were randomly selected from each auditor's list of patients that had already been abstracted by the nurses. The complete Kappa tests for the charts audited were shown in Appendix 2.

The "*" in Appendix 2 specifies that Kappa value was 100%. Over 90% of Kappa values were 100% and the remaining ones were either excellent (>80%) or Very Good (60-80%). Only 3 kappa values were less than 60% and they were 49%, 58% and 59%. This high quality of abstracting was the result of the intensive training that the abstractors received and the requirements that for the 10 practice cases their Kappa (agreement) values be at least 90% prior to being allowed to abstract in the field. The additional day of training that the auditors received prior to entering the field also contributed.

V. Screening Rate Calculations

For the purpose of this analysis, the screening rate calculation is defined as screening that occurred during a fifteen-month time period from 5/1/98 to 7/31/99. If a patient's breast care was provided by other physicians such as an OB/GYN, or if the patient was being followed by an oncologist, this was recorded in the database, and the patient was excluded from our screening rate calculations. Mammograms ordered for diagnostic rather than for screening

purposes, either on the basis of an unresolved mammographic abnormality or an abnormal CBE, were not considered to be a screening mammogram and this patient was also excluded from the mammography screening rate. Similarly, patients with a diagnostic CBE, which is defined as a CBE performed after knowledge of abnormal mammogram results, were also excluded. Comments concerning each breast care related encounter, such as refusal and the reason why the tests were not done, were recorded and were subsequently reviewed.

For this analysis, women were classified as being "screened" if they had received at least one CBE or Mammogram, or both within the 15-month period between 5/1/98 and 7/31/99.

The following screening rates or issues related to screening rates were calculated:

- (1) The CBE screening rate defined by an actual CBE performed in asymptomatic women
- (2) The mammography screening rate defined by an actual mammogram performed in asymptomatic women
- (3) The BC (both CBE and mammography) screening rate defined by both CBE and mammography performed in asymptomatic women.
- (4) The rates of CBE recommended, regardless of whether or not they were performed.

- (5) The rates of mammography that are ordered, regardless of whether or not they were performed.
- (6) The time interval between performance of CBE and mammography for asymptomatic women who had both examinations. The four time periods chosen for evaluation were: 3 month, 3-6 months, 6-9 months, and >9 months.
- (7) The time intervals between when a mammogram was ordered and when it was actually done, according to the four intervals described above.
- (8) The compliance rate for CBE and mammography: percentages of women who refused mammography or CBE upon recommendation.
- (9) The reasons for refusal if documented in charts and other reasons why mammography or CBE was deferred or not performed.
- (10) The percentages of women who received an annual well-women exam.
- (11) The percentages of CBE performed and mammograms ordered during annual well-women exams.
- (12) The BC screening rate among women who did not receive an annual well women exam.
- (13) The screening rates broken down by age groups: women 40-49 and women 50-69.
- (14) The association between the total numbers of visits to the family practice physicians during the 15-month study period and the BC screening rates. Total numbers of visits were grouped into 1-2 visit(s), 3-4 visits, and beyond 5 visits. Because we collected the total number of visits not only between 5/1/98 to

7/31/99, but also included visits that occurred before 5/1/98, the total number of visits can only serve as a proxy indicator.

VI. Statistical Analysis

Odds ratios (OR) and 95% confidence intervals (CI), derived from logistic regression models, were calculated to ascertain the association between the total numbers of visits to the family practice physicians during the 15-month study period and the BC screening rates.

CHAPTER 3. RESULTS

I. Sample Size

The numbers of patients assessed for eligibility in the three sites were 540, 872, and 896 (Table 4). Among them, the numbers of patients who were ineligible for analysis were: 23 (4.3%), 94 (10.8%), and 25 (2.8%). These are the patients who were male, not active during the last 3 years, outside the stated age range, or whom breast care was not provided by a family practice provider (Figure 1). The numbers of eligible women were 517 (95.7%), 778 (89.2%), and 871 (97.2%) at site G, H and I, respectively. These women presented at least once to the office during the last 3 years and represented the population that should have received a CBE and mammogram.

Two BC screening rates were generated as follows:

1. BC screening rates among GROUP A women (those who had at least one office visit for any reason or had a phone call/reminder that's breast related during 8/1/98 and 7/31/99). The numbers of patients who met those criteria were 398 (73.7%), 653 (74.9%), and 505 (56.4%), in site G, H and I, respectively. The percentage of eligible women who were seen between 8/1/98 and 7/31/99 and in whom no breast care was performed

were 87 (16.1%), 205 (23.5%) and 219 (24.5%), in Site G, H and I, respectively (Table 4).

2. BC screening rates among GROUP A and GROUP B women. GROUP B women were those who presented at least once to the office during the last 3 years, but did NOT have one office visit for any reason or have a phone call/reminder that's breast related during 8/1/98 and 7/31/99. The numbers of patients under this description in the three sites were: 119 (22%), 125 (14.3%), and 366 (40.8%) at site G, H and I, respectively. These women were included only in the denominator of our screening rates, because they had no breast care activities during our study period (Table 4).

Figure 1 showed details of the screening rate calculation.

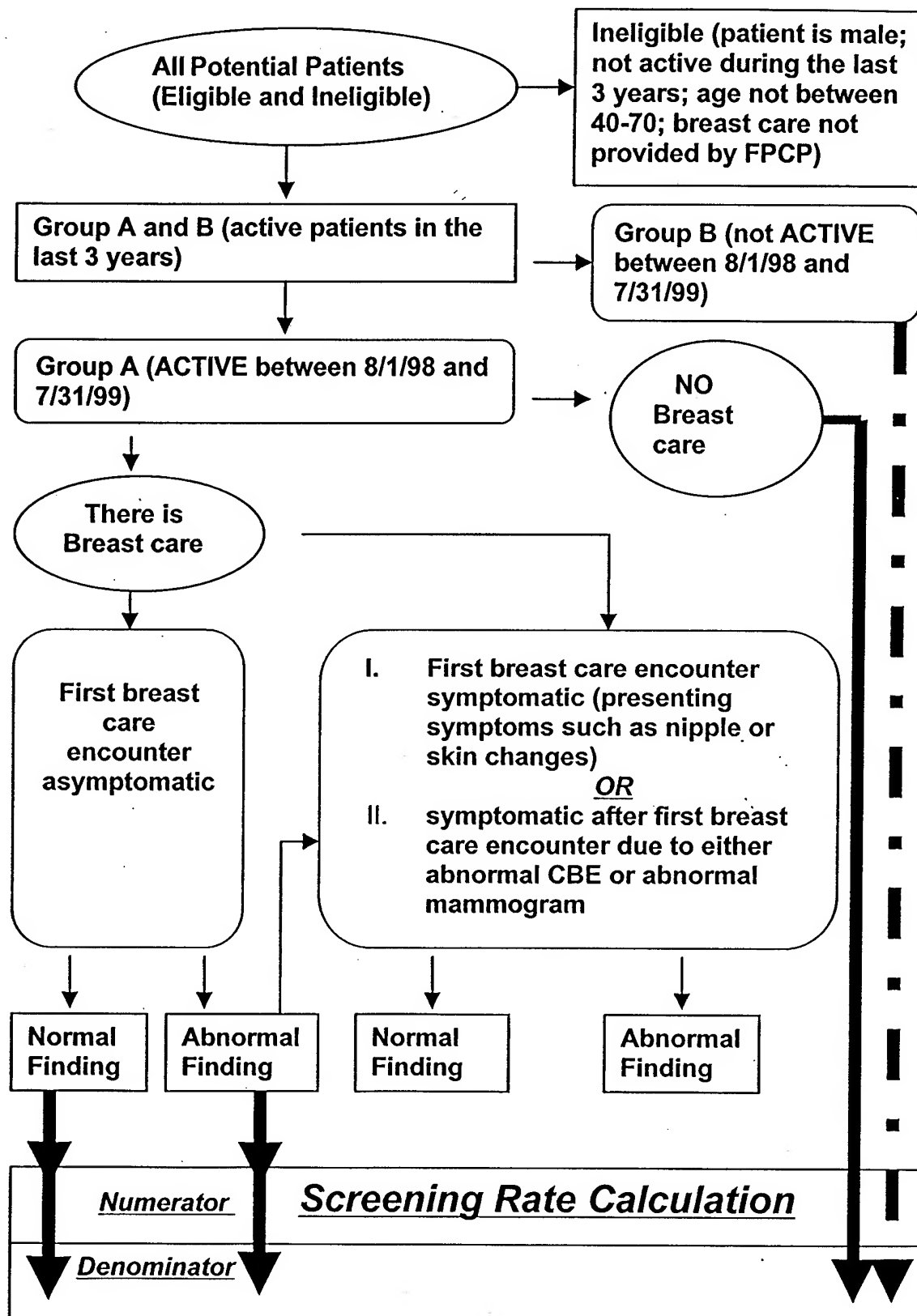
**Table 4. Numbers And Percentages of Eligible Women In The Three Clinics,
Broken Down By Eligibility Criteria**

	Eligible Women			Ineligible Women	Total
	Group A ¹		Group B ²		
	With Breast Care	Without Breast Care			
Site G	311 (57.6%)	87 (16.1%)	119 (22.0%)	23 (4.3%)	540
Site H	448 (51.4%)	205 (23.5%)	125 (14.3%)	94 (10.8%)	872
Site I	286 (31.9%)	219 (24.5%)	366 (40.8%)	25 (2.8%)	896

1 = Eligible women who have had one office visit to the family practice clinic for any reason or had a phone call/reminder that's breast related during 8/1/98 and 7/31/99

2 = Eligible women who did not have one office visit to the family practice clinic for any reason or had a phone call/reminder that's breast related during 8/1/98 and 7/31/99

Figure 1: Logistic Flow Chart



II. BC screening rates during the 15-month study period

Table 5 and 6 shows the BC screening rates in women who had at least one office visit to the family practice clinic for any reason or had a phone call/reminder that's breast related during 8/1/98 and 7/31/99.

Our results shows that the percentages of CBE and mammography conducted differed between women older than 50 years and younger than 50.

For CBE, women older than 50 had higher, lower, and equal rates at clinic G, H and I, respectively, compared to women younger than 50. Among clinics G, H and I, the overall percentages of women who received at least one CBE were 53.0%, 45.2%, and 27.0%, respectively (Table 5). Among women aged 40-49, the rates were 44.0%, 49.2%, and 25.8%. Among women 50 years and older, the rates were 59.9%, 41.5%, 28.1% (Table 6).

For women aged 50 and older, the mammography screening rates were consistently higher than for women younger than 50, in all three clinics. The percentages of women who had at least one mammogram during the study period were 52.3%, 32.5%, and 28.0%, in the three clinics, respectively (Table 5). Among women aged 40-49, the rates were 41.5%, 24.4%, and 21.7%. Among women 50 years and older, the rates were 60.8%, 40.0%, and 34.0%(Table 6).

The percentages of women who had both CBE and mammogram were 35.8%, 22.8%, and 16.7%, in site G, H and I, respectively (Table 5). Among women aged 40-49, the rates were 26%, 19%, and 14%. Among women 50 years and older, the rates were 45%, 27.3%, and 19.7% (Table 6).

Table 7 shows the BC screening rates among women in GROUP A and GROUP B. It also demonstrate the rates in women who DID NOT have at least one office visit to the family practice clinic for any reason or had a phone call/reminder that's breast related during 8/1/98 and 7/31/99. With the inclusion of this latter group, the screening rates were even lower (Table 7). In site I, <10% of all women received both CBE and mammogram.

III. Time intervals between CBE and mammography

We examined the time interval between performance of CBE and mammography for asymptomatic women who had both examinations. Our results showed that in all three sites, CBE and mammography were performed within three months of one another 90-91% of the time (Table 5).

IV. Time intervals between when mammography was ordered and actually performed

We also evaluated the time interval between when a mammogram was ordered and when it was actually done. Among women who had at least one mammogram, 98.3%, 93.9%, and 96.2% of them had less than 3-month time intervals between the time that mammogram was ordered and when it was actually performed, in site G, H and I, respectively (Table 5).

Table 5. Annual BC Screening Rates Among Group A Women

	Site G	Site H	Site I
CBE ordered	58.7%	54.7%	28.8%
CBE performed	53.0%	45.2%	27.0%
Mammogram ordered	63.5%	42.9%	44.2%
Mammogram performed	52.3%	32.5%	28.0%
BC screening rate (within 3 month)	32.4%	20.7%	15.1%
BC screening rate (both done any time)	35.8%	22.8%	16.7%
Both tests done within 3 month	91.0%	91.0%	90.0%
Mammogram done within 3 month of recommendation	77.3%	60.2%	56.2%
Mammogram done anytime after recommendation	78.6%	64.1%	58.4%
Mammogram done within 3 month of recommendation	98.3%	93.9%	96.2%

Table 6: Annual BC Screening Rates By Age Groups

	SITE G			SITE H			SITE I		
	40-49	>50	Total	40-49	>50	Total	40-49	>50	Total
CBE ordered	50.6%	65.0%		55.0%	54.5%		26.9%	30.6%	
CBE done	44.0%	59.9%		49.2%	41.5%		25.8%	28.1%	
Mammogram ordered	51.8%	72.7%		35.6%	49.5%		33.6%	55.3%	
Mammogram done	41.5%	60.8%		24.4%	40.0%		21.7%	34.0%	
Both done	25.9%	45.1%		19.0%	27.3%		13.7%	19.7%	
Total n = (among group A women only)	173	225	398	315	338	653	259	246	505
Total n = (among all patients)	242	298	540	435	437	872	467	429	896

**Table 7: Annual BC Screening Rates By Age Groups Including
Women In Group B**

	SITE G			SITE H			SITE I		
	40-49	>50	Total	40-49	>50	Total	40-49	>50	Total
CBE ordered	37.6%	50.7%		43.9%	47.7%		15.2%	17.8%	
CBE done	32.7%	46.8%		39.3%	36.3%		14.6%	16.4%	
Mammogram ordered	38.3%	56.3%		28.3%	43.3%		18.8%	32.5%	
Mammogram done	30.6%	47.0%		19.4%	35.0%		12.1%	20.0%	
Both done	15.7%	31.5%		13.7%	20.8%		7.0%	9.9%	
Total n = (among women in group A and group B)	231	286	517	393	385	778	456	415	871
Total n = (among all patients)	242	298	540	435	436	871	467	429	896

V. BC screening rates during an annual well-woman exam

The percentages of women in GROUP A who received an annual well-women exam were 58.0%, 43.5%, and 20.7% in site G, H, and I, respectively, during the period of 5/1/98 and 7/31/99. Among women 40-49, the percentages were 52.0%, 47.6%, and 18.1%. Among women 50 years and older, the percentages were 62.7%, 39.7%, and 20.7% (Table 8).

Table 8 shows the screening rates for women who received a well woman exam. Among women 40-49 years old, the percentages received CBE during a well woman exam were 76.7%, 95.9%, and 87.2%, in the three clinics respectively. For women 50 years and older, the percentages were 83%, 93.1%, and 76.5%. Women 50 years and older consistently received more frequent recommendations for mammography during a well woman exam than those younger than 50. The percentages were 63.5%, 51.9%, and 73.9%, for women 40-49 years old. Among women 50 years and older, the rates were 85.7%, 84%, and 91%.

Table 9 demonstrated that of all of the CBE performed during the study period, most were done during a well woman exam. In site G, among women aged 40-49, 93.2% of CBE was done during a well woman exam; among women age 50 years and older, 90% were done during a well woman exam. In site H, for women aged 40-49, 92.8% of CBE was done during an annual exam, and 89%

for women 50 years and older. In site I, among women aged 40-49, 62.1% of CBE were done during a well woman exam, and 57.4% for women aged 50 years and older. Table 9 further illustrates the percentages of mammograms that were recommended during an annual well-women exam. In site G, for women aged 40-49, the percentage of mammograms that were recommended during a well woman exam was 63.5%, and for women 50 years and older, the percentage was 75%. In site H, among women aged 40-49, the percentage was 63.9%, and for women 50 years and older, the percentage was 56%. In site I, for women aged 40-49, the percentage was 40%, for women 50 years and older, the percentage was 30%.

**Table 8: Screening Rates In Women Who Received A Well
Woman's Exam (WW) Between 5/1/98 and 7/31/99**

	SITE G		SITE H		SITE I	
	40-49	>50	40-49	>50	40-49	>50
CBE ordered	76.7%	83.7%	98.0%	94.7%	87.2%	76.5%
CBE done	76.7%	83.0%	95.9%	93.1%	87.2%	76.5%
Mammogram ordered	63.5%	85.7%	51.9%	84.3%	73.9%	91.0%
Total n	90	141	147	131	47	51
% of women had a WW (among GROUP A women)	52.0%	62.7%	47.6%	39.7%	18.1%	20.7%

**Table 9: Percentages of CBE Performed And Mammography
Recommended During WW**

	SITE G		SITE H		SITE I	
	40-49	>50	40-49	>50	40-49	>50
CBE Done in WW	69	117	141	122	41	39
Total CBE Done	74	130	152	137	66	68
Percentage of CBE Done in WW	93.2%	90.0%	92.8%	89.1%	62.1%	57.4%
Mammogram Ordered in WW	54	114	69	91	34	40
Total Mammogram ordered	85	152	108	162	85	135
Percentage of Mammogram ordered in WW	63.5%	75.0%	63.9%	56.2%	40.0%	30.0%

VI. BC screening rate among women who did not receive an annual well-woman exam between 5/1/98 and 7/31/99

Among women who did not receive an annual exam during our study period, the percentages of women who received CBE (during office visits for other medical reasons) were 6.0%, 6.8%, 11.8% for women 40-49 years, in clinics G, H, and I, respectively. For women 50 years and older, the percentages were 15.5%, 8%, and 14.9% (Table 10).

The percentages of mammograms ordered in patients who were not seen for annual well-women exams (but during other office visits, or as a result of phone or card reminders) were 37.3%, 24.1%, and 24.1% for women 40-49 years, in clinics G, H and I, respectively. Among women 50 years and older, the rates of mammography recommendation were 46.4%, 36%, and 48.7% (Table 10).

**Table 10: Screening Rates Among Women Who
Did Not Receive a Well Women (WW) Exam
During 5/1/98 and 7/31/99**

	SITE G		SITE H		SITE I	
	40-49	>= 50	40-49	>= 50	40-49	>= 50
CBE Done	5	13	11	15	25	29
Total n of women without WW	83	84	162	199	212	195
Percentage of CBE Done not in WW	6.0%	15.5%	6.8%	7.5%	11.8%	14.9%
Mammogram Ordered in WW	31	39	39	71	51	95
Total n of women without WW	66	62	125	175	212	195
Percentage of Mammogram ordered not in WW	37.3%	46.4%	24.1%	35.7%	24.1%	48.7%

VII. Compliance rate

Only 0.5-2% of women who had a CBE recommended refused the examination at the time of the office visit. The refusal rates for recommended mammography were 0.8-2% at the time of recommendation by the family practice physician. Table 11 lists the various reasons and total number of patients who refused, if they were recorded in the medical charts.

Table 11: Reasons And Numbers of Refusals When Test Is Recommended

	Reasons	Numbers
Site G	Refusal with no explanation	3
	Refused mammogram because it's too painful	1
Total		4
Site H	Due to insurance	4
	Refusal with no explanation	5
	Cited physician time restraint	3
	CBE deferred due to menstruating	1
	CBE deferred due to medical reasons / post surgical braces	1
Total		14
Site I	Due to insurance	2
	Refusal with no explanation	1
Total		3

VIII. The association between the total numbers of visits and the BC screening rates

The association between the total numbers of visits during the 15-month period (proxy indicator), prior to the last office visit during 8/1/98 and 7/31/99, and the BC screening rates was also analyzed. We made the assumption that each office visit represented an equal and independent opportunity for a CBE, and each office visit/phone call consultation represented an equal and independent opportunity for a mammography referral. Therefore, the likelihood of obtaining a CBE or mammogram should increase predictably with each additional visit.

In Site G, the total numbers of visits among ACTIVE patients ranged from 1 to 28. In site H, the numbers ranged from 1 to 29. In site I, the number ranged from 1 to 34. Logistic regression was used to analyze the association between the total visits and the BC screening rates. Table 12 shows that in all three sites, mammography screening rates were significantly higher for those with beyond 5 visits, compared to those with 1-2 visit(s). In site I, CBE ordering and performed were significantly higher for those patients with beyond 3 visits than those with 1-2 visit(s). In addition, the screening rates of BC (both CBE and mammography) in site I were higher for those with beyond 5 visits.

Table 12. Odds Ratios and 95% Confidence Intervals For the Association Between Total Number of Visits and BC Screening Rates

Site G	N	CBE ordered	CBE done	Mammo- gram ordered	Mammo- gram done	Both done
Total visit: 1-2	53	1.0	1.0	1.0	1.0	1.0
Total visit: 3-4	84	0.96 (0.47- 1.95)	1.13 (0.56- 2.62)	1.53 (0.76- 3.07)	1.52 (0.76- 3.06)	1.18 (0.55- 2.55)
Total visit: beyond 5	198	0.92 (0.49- 1.72)	0.94 (0.51- 1.73)	2.21 (1.19- 4.11)	2.25 (1.21- 4.18)	1.56 (0.79- 3.06)
Site H		CBE ordered	CBE done	Mammo- gram ordered	Mammo- gram done	Both done
Total visit: 1-2	101	1.0	1.0	1.0	1.0	1.0
Total visit: 3-4	120	1.12 (0.65- 1.91)	1.25 (0.74- 2.13)	1.12 (0.65- 1.91)	1.2 (0.66- 2.19)	0.97 (0.49- 1.91)
Total visit: beyond 5	318	1.13 (0.72- 1.78)	1.2 (0.77- 1.89)	1.29 (0.82- 2.03)	1.99 (1.2- 3.3)	1.33 (0.76- 2.34)
Site I		CBE ordered	CBE done	Mammo- gram ordered	Mammo- gram done	Both done
Total visit: 1-2	107	1.0	1.0	1.0	1.0	1.0
Total visit: 3-4	88	2.13 (1.05- 4.33)	1.92 (0.92- 4.0)	4.41 (2.26- 8.59)	2.24 (0.93- 5.4)	3.95 (1.04- 15.1)
Total visit: beyond 5	287	2.56 (1.42- 4.6)	2.54 (1.39- 4.63)	5.33 (3.02- 9.4)	5.3 (2.57- 11.0)	7.14 (2.18- 23.4)

CHAPTER 4 DISCUSSION

I. BC screening rates

Our results showed that 25.8 – 59.9% of women in the three clinics received CBE, 21.7 – 60.8% received mammography and 13.7 – 45.1% received both CBE and mammography during our study period. These screening rates are far short of the Healthy People 2000's recommended mammography and CBE combined screening rate of 60%.

In addition, we found that in all three clinics, the mammography screening rates were consistently higher among women 50 years or old, compared to those less than 50. This seemed to be consistent with the current mammography screening guidelines: every major professional organization recommends mammographic screening in women 50-69 at intervals of 1-2 years [3]. However, recommendations are inconsistent for women aged 40-49 and 70 and over.

CBE screening rates varied by site. In Site H, screening rates for CBE were higher among women younger than 50 than those greater than 50, while in Site G, the reverse was true. In site I, women less than 50 and greater than 50 had the same CBE screening rates.

II. Time intervals

Our results showed that over 90% of mammograms and CBEs were done within 3 months. The same applied to the time interval between when mammography was ordered and when it was actually performed.

The potential explanation for why most mammograms were performed within three months was that the impact of a physician's recommendation was most likely to be the strongest close to the time it is made. Longer intervals between the time the test was recommended and actually performed may have diluted the motivation inspired by the physician's recommendation.

III. BC screening during an annual exam

Consistent with Conry's results [43], we found that the percentages of CBEs performed during an annual exam were very high in all three sites. The percentages of women who received mammography recommendations from the family practice physicians were also high during a well woman exam. These results can be confirmed by the fact that extremely low percentages of women with no well woman visit received CBE during our study period. At least in two sites (site G and site H), over 90% of CBE was performed during an annual well-women exam.

The percentages of women with no annual exam who received a mammography recommendation were high. This may reflect the fact that mammograms can be ordered by phone or mammogram reminders, in addition to office visit.

However, we also showed that percentages of women who received an annual well-women exam during our study period are relatively low in all three sites (18.1 – 62.7%). Interventions should be carried out to improve physician and patients' education about the importance of a well woman exam.

IV. Total numbers of office visits and the screening rates

Our results demonstrated that the total number of visits made by a woman during the 15-month period is related to higher screening rates. We found that among all three sites, the mammography performed rates were higher for women with beyond 5 visits, as compared to those with only 1-2 visit(s). In site I, the CBE ordered and performed rates were also higher for this group, as compared to those with only 1-2 visits.

McCarthy et al also found that the mammography rate was related to the number of visits a patient had [36]. Women who had 2-10 visits had the highest mammography use, compared to those with 1 visit or with visits beyond 10. Among women with more than 10 visits, the rate is lower probably due to the fact

that these patients have other severe and more pressing chronic illnesses that focus attention away from preventive health measures.

However, other investigators found that total numbers of visits are not related to the screening rate [31].

V. Chart audit vs. self-reported interviews

It has generally been observed that there may be substantial differences between information obtained from medical records audits and that obtained from patient self-reported interviews. Whitman et al tried to determine whether chart reviews and interviews provide the same information about breast cancer screening [39]. They collected the percentage of women older than 40 who received a breast exam, and the percentages of women aged older than 50 who received a mammogram at two different public health clinics in Chicago. They used both chart reviews and telephone interviews of women participants. They found that interviews significantly estimated higher proportions of women receiving breast exam and mammograms in the previous 12 months interval than were estimated from randomly selected medical records. There are several possible reasons for the discrepancies: first the medical records may be incomplete; second the women being interviewed may incorrectly recall the time when the test was performed, or even which test they obtained; third women could be recalling tests they have done outside the clinics. Their results

suggested that precautions should be taken on the usage of survey data as measures of actual performance. It should be accompanied by comparing these measures with data of actual performance at the medical record level.

VI. Interventions to increase BC screening rates

One strategy for increasing BC screening rates is to enhance physician referrals. A physician's recommendation is one of the most important predictors that a woman will receive a screening mammogram. A better understanding of the factors that influence physician's referral behavior is critical in designing strategies to increase population coverage of BC screening. Enhancing mammography referrals from primary care physicians is of particular public health importance because they see a broad demographic and geographic spectrum of women. Physicians' screening mammography referral rates have been found to vary by physician age, gender, and knowledge or attitudes. Compared with older physicians, younger physicians have a greater tendency to incorporate preventive care into their practice, to disagree less with evidence-based guidelines, and to favor a more frequent screening interval for BC screening [32] [33] [34] [35] [44].

Fletcher et al tested whether a community-wide intervention could increase the usage of mammography screening for BC [45]. They conducted a controlled study from 1/87 to 1/90 in two Eastern North Carolina communities.

During 1989, interventions were developed and aimed at primary care physician and community participating women. Physicians underwent training sessions about CBE skills. To reach community women, they used local media and organizations. They also reviewed medical charts to determine the percentage of women the physicians had referred for mammography. They found that the percentage of women who reported receiving a mammogram increased from 35 to 55% in the experimental community and from 30 to 40% in the control community. The intention to get a mammogram among eligible women was also significantly increased. Physician reports and medical record reviews in the communities showed similar increases in the number of mammograms ordered.

VII. Study strengths

One strength of this study was that we abstracted medical records to calculate BC screening rates in the three Michigan clinics. Summary sheets were made for all breast care related visits that were recorded and reviewed manually. CBE or mammography performed for diagnostic, rather than screening, purposes were identified and excluded. Our sample sizes for clinics G, H and I were 540, 872, and 896, respectively. In addition, we performed a very comprehensive BC screening rate calculation, including the ordered and performed rates of CBE and mammography alone or combined, time interval between CBE and mammography, time interval between when a mammography was ordered and when it was performed, compliance rates for CBE or mammography after

recommendation, BC screening rates during well-woman exams. In addition, the screening rates were broken down to women 40-49 and women 50-69, in order to reflect the different national guidelines for the two age groups.

VIII. Study limitations

In interpreting results from the analysis, some limitations should be considered. First, some CBE or mammography recommendations may have been performed or verbal without being documented in the medical record. Second, the chart audit may not be 100% reliable due to missing information. For example, mammograms could have been performed elsewhere and not documented in the charts.

In addition, though not a limitation of the screening rate calculations reported, it would have been more helpful if we had collected some other potential screening rate predictors, such as social economic status and insurance coverage for all patients in the different clinics. These variables might contribute to the differences in the screening rates among different sites.

CHAPTER 5 CONCLUSION

Our results underline two important points: (1) the current BC screening rates for CBE and mammography individually or combined are unacceptably low in the three family practice clinics we studied and (2) when screening is recommended, compliance with the recommendation is above 98% and accomplished 90% of the time within 3 months. To meet the Healthy People 2000 recommended mammography and CBE combined screening rate of 60%, interventions to improve these findings at family practice clinics is urgently needed.

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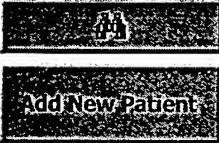

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Appendices

Appendix 1

Form I- Front-End Form

	Patient Name (Last):	testing	
	(First):		
	Medical Record Number:		
	Date Of Birth:		
	Abstractor's ID:		

Eligibility Criteria: Check One Item For Each Statement (1-5)

1. Patient gender is:
2. Patient has been seen in last three years
3. Patient birthday is between August 1, 1928 and July 1, 1959
4. Breast health care provided by
5. Active patient between 8/1/98-7/31/99

Meaning of Eligibility Code:

For site number 1-5:

- 1= Eligible for abstract and insertion
- 2= Eligible for insertion only
- 3= Ineligible

For site number 6-9:

- 1= Eligible for abstract
- 2 or 3= Ineligible



Rules for Assigning Study ID:

Study ID is a 6-digit number. The first digit is your site number. The second digit is the Eligibility code shown in the box above. The rest four digits are consecutive numbers starting 0001.

Please assign study ID:

1

Today's Date:

11/11/11

For your reference, please look in the box on the right, find out what was the last number assigned for that specific eligibility category, and use the next consecutive number.

For eligibility code =

110267

For eligibility code =

120183

For eligibility code =

130202





Chart Review Form (Only For Eligible Patient)

Study ID:

1

1. Date of Most Recent Office Visit (MM/DD/YY):

2. Autocalculated Date For the Last Eligible Visit Within the Last 15 months (MM/DD/YY):

3. Total Number of Visits Within 15 Months, Including The Most Recent Visit:

4. Was A Breast Care Performed During Any of The Visits Within The 15 Months Period:

5. Personal/Family History Of Breast Cancer?

Add New Patient

Rule for filling in the age at diagnosis:

- 1) Fill in exact age when information is available;
- 2) Fill in '777' if only known Pre-menopausal equal to or less than 50 years of
- 3) Fill in '888' if only known Post-menopausal or greater than 50 years old;
- 4) Fill in '999' if no information is available.

In Self? ☐ No , Age:

Surgery/Reconstruction:

- ☐ Complete Breast Removal ☐ Partial Breast Removal/Lumpectomy
☐ Prophylactic Implants ☐ Autologous Reconstitution
☐ Other, specify
☐ Undocumented

Treatments (check all that apply)

- ☐ Chemotherapy ☐ Radiation ☐ Tamoxifen/Nolvadex
☐ Alternative medicine(s), specify
☐ Other, specify
☐ Undocumented

In Mother? ☐ No , Age:

In Sister? ☐ No , Age:

In Daughter? ☐ No , Age:

In Other Relatives? ☐ No , Please specify:

☐ Sister2 Age:

☐ Daughter2 Age:

BOX-A Record information for patient's each visit when a breast care was performed. Start with the first visit when any breast care activity was recorded during that 15 months period. Click the button on the right to continue.

Continue to record visit info.

Go To First Patient

Go To Previous Patient

Go To Next Patient

Go To Last Patient

(Click Any of the Buttons Above to Navigate the Record)

Form II- Visit Entry

Add New Visit	Go To First Visit	Go To Previous Visit	Go To Next Visit	Go To Last Visit
---------------	-------------------	----------------------	------------------	------------------

Study ID: 1

Go Back to Front-End

Please fill out Question 6 and Question 7 for every visit/call.

6. Date of Breast Care Activity Was Recorded: 11/11/11

Type of Contact:

If this visit is about a test result, you can directly go to Test Result Form, without filling out CBE documentation

7. Purpose of this Visit/Call:

Specify:

Go Directly to Test Result Form

8. Who Performed Breast Care/Phone Consultation? (Check All That Apply)

- ☐ Resident Physician ☐ Faculty Physician ☐ Physician Assistant ☐ Nurse Practitioner

9. Patient Presenting Symptoms/Signs (Check All That Apply)

Which breast(s) has presenting symptom?

If you don't know which breast, please record information in "Left Breast" category.

Left Breast:

Right Breast:

- ☐ None ☐ Undocumented/Don't know
- ☐ Lump(s)/Mass(es)/Asymmetrical thickening
- ☐ Nipple Discharge
- ☒ Skin/Nipple change (check all that apply)
- ☐ Skin Dimpling ☐ Erythema/Skin thickening
- ☐ Nipple Retraction ☐ Nipple Scaling
- ☐ Pain/Tenderness
- ☒ Occult Mammographic Abnormality
- ☐ Density(Nodule or Asymmetry)
- ☐ Microcalcifications
- ☐ Other, specify:

- ☐ None ☐ Undocumented/Don't know
- ☐ Lump(s)/Mass(es)/Asymmetrical thickening
- ☐ Nipple Discharge
- ☒ Skin/Nipple change (check all that apply)
- ☐ Skin Dimpling ☐ Erythema/Skin thickening
- ☐ Nipple Retraction ☐ Nipple Scaling
- ☐ Pain/Tenderness
- ☒ Occult Mammographic Abnormality
- ☐ Density(Nodule or Asymmetry)
- ☐ Microcalcifications
- ☐ Other, specify:

10. CBE Documentation:

11. CBE Findings (Check All That Apply):

- ☐ Bilateral Implants
- ☒ Previous abnormality resolved
- ☐ Lump/mass resolved ☐ Observational finding resolved ☐ Nipple discharge resolved ☐ Pain gone
- ☐ Normal/Symmetrical nodularity/Symmetrical fibrocystic(Fill Out Quality of CBE Documentation)
- Quality of Written Description of CBE Documentation (Check All That Apply):

<input type="checkbox"/> Inspection, specify:	Nipple Change	Undocumented	Breast Size/Sha	Undocumented
	Scar	Undocumented	Skin Change	Undocumented
<input type="checkbox"/> Palpation, specify:	Fibrocystic Bre	Undocumented	Nodularity	Undocumented
	Mass(es)	Undocumented	Pain/tenderness	Undocumented
<input type="checkbox"/> Lymph node examination	Adenopathy/Axillary Nodes		Undocumented	
<input type="checkbox"/> No specific documentation besides normal				
<input type="checkbox"/> Other, Specify: _____				

Abnormal: Which breast(s) has abnormal finding?	
If you don't know which breast, please record information in "Left Breast" category.	
Left Breast:	Right Breast:
Location: _____	Location: _____

☐ Lump(s)/Mass(es)/Asymmetric breast thickening/
Asymmetric Fibrocystic

Lump size:

Depth:

Hardness:

Mobility:

Shape:

Texture:

Additional Findings With Lumps (check all that apply):

Skin Dimpling/Retractio	Undocumented
Skin Erythema	Undocumented
Skin Peau d'orange or Skin Thickening	Undocumented
Nipple Retracti	Undocumented
Nipple Scaling	Undocumented
Pain/Tenderness	Undocumented
Fibrocystic Breast(s)	Undocumented
Nipple Discharge	Undocumented
<input type="checkbox"/> Other, Specify: <input type="text"/>	

☐ Nipple Discharge With No Lump

Spontaneous?

Color

Unilateral or bilateral?

Single or multiple ducts?

☒ Observational Findings With No Lump

☐ Skin dimpling/retraction

☐ Skin Erythema

☐ Skin Peau d'orange/Skin Thickening

☐ Nipple retraction

☐ Nipple scaling

☒ Pain

☐ Breast pain

☐ Chest wall pain

☐ Unspecified

☐ Other, specify:

☐ Lump(s)/mass(es)/Asymmetric breast thickening/
Asymmetric Fibrocystic

Lump size:

Depth:

Hardness:

Mobility:

Shape:

Texture:

Additional Findings With Lumps (check all that apply):

Skin Dimpling/Retractio	Undocumented
Skin Erythema	Undocumented
Skin Peau d'orange or Skin Thickening	Undocumented
Nipple Retraction	Undocumented
Nipple Scaling	Undocumented
Pain/Tenderness	Undocumented
Fibrocystic Breast(s)	Undocumented
Nipple Discharge	Undocumented
<input type="checkbox"/> Other, Specify: <input type="text"/>	

☐ Nipple Discharge With No Lump

Spontaneous?

Color

Unilateral or bilateral?

Single or multiple ducts?

☒ Observational Findings With No Lump

☐ Skin dimpling/retraction

☐ Skin Erythema

☐ Skin Peau d'orange/Skin Thickening

☐ Nipple retraction

☐ Nipple scaling

☒ Pain

☐ Breast pain

☐ Chest wall pain

☐ Unspecified

☐ Other, specify:

Quality of Written Description of CBE Documentation For Abnormal Findings (Check All That Apply):

<input type="checkbox"/> Drawing of abnormal findings				
<input type="checkbox"/> Inspection, specify:	Nipple Change	Undocumented	Breast Size/Sha	Undocumented
	Scar	Undocumented	Skin Change	Undocumented
<input type="checkbox"/> Palpation, specify:	Fibrocystic Breast	Undocumented	Nodularity	Undocumented
	Mass(es)	Undocumented	Pain/tenderness	Undocumented
<input type="checkbox"/> Lymph node examination				
Adenopathy/Axillary Nodes		Undocumented	Lymph Node Enlarged?	
<input type="checkbox"/> Other, Specify: <input type="text"/>				

**Go To
Followup Form**

**Go To Test Result
Form**

Form III-Test Result Entry

Study ID: **1**

Date of the Visit: **11/11/11**

12. Mammogram Documentation:

1. Ordered/Recommended/Encouraged	<input type="text"/>	Date:	<input type="text"/>
2. Mammogram Performed	<input type="text"/>	Date:	<input type="text"/>
3. Results Obtained	Stamped/Documented? <input type="text"/>	Date:	<input type="text"/>
4. Results Reviewed By FPCP	Signed/Documented? <input type="text"/>	Date:	<input type="text"/>

13a. Mammogram Findings: Final Impressions Which Breast?

If you don't know which breast, please record information in "Left Breast" category.

Left Breast:

Right Breast:

<input type="checkbox"/> Normal/No Finding Identified/Category I <input type="checkbox"/> Normal/Benign-appearing abnormality/Category II <input type="checkbox"/> Probably benign/possibly malignant, indeterminate/Category III <input type="checkbox"/> Suspicious for malignancy/Category IV <input type="checkbox"/> Malignant until proven otherwise/Category V <input type="checkbox"/> Other: Specify: <input type="text"/>	<input type="checkbox"/> Normal/No Finding Identified/Category I <input type="checkbox"/> Normal/Benign-appearing abnormality/Category II <input type="checkbox"/> Probably benign/possibly malignant, indeterminate/Category III <input type="checkbox"/> Suspicious for malignancy/Category IV <input type="checkbox"/> Malignant until proven otherwise/Category V <input type="checkbox"/> Other: Specify: <input type="text"/>
--	--

13b. Mammogram Findings: Description Which Breast?

If you don't know which breast, please record information in "Left Breast" category.

Left Breast:

Right Breast:

☐ Asymmetric Breast: more in which breast:

<input type="checkbox"/> Bilateral Implants <input type="checkbox"/> Radiolucent Breasts <input type="checkbox"/> Dense Breasts/Dense Nodular Breasts <input type="checkbox"/> Rounded density(ies), most likely cyst or fibroadenoma <input type="checkbox"/> Irregular Density(ies) <input type="checkbox"/> Benign Appearing Calcifications <input type="checkbox"/> Suspicious Calcification <input type="checkbox"/> Calcified Fibroadenomas <input type="checkbox"/> Axillary Lymph Nodes <input type="checkbox"/> Other, specify: <input type="text"/>	<input type="checkbox"/> Bilateral Implants <input type="checkbox"/> Radiolucent Breasts <input type="checkbox"/> Dense Breasts/Dense Nodular Breasts <input type="checkbox"/> Rounded densities, most likely cyst or fibroadenoma <input type="checkbox"/> Irregular Density(ies) <input type="checkbox"/> Benign Appearing Calcifications <input type="checkbox"/> Suspicious Calcification <input type="checkbox"/> Calcified Fibroadenomas <input type="checkbox"/> Axillary Lymph Nodes <input type="checkbox"/> Other, specify: <input type="text"/>
--	---

13c. Mammogram Findings: Location For Category II and Up Which Breast?

If you don't know which breast, please record information in "Left Breast" category.

IF AREA NOT SPECIFIED, check SCATTER/THROUGHOUT Breast category

Left Breast Location:

Right Breast Location:

<input type="checkbox"/> Upper Outer Quadrant	<input type="checkbox"/> Lower Outer Quadrant	<input type="checkbox"/> Upper Outer Quadrant	<input type="checkbox"/> Lower Outer Quadrant
<input type="checkbox"/> Upper Inner Quadrant	<input type="checkbox"/> Lower Inner Quadrant	<input type="checkbox"/> Upper Inner Quadrant	<input type="checkbox"/> Lower Inner Quadrant
<input type="checkbox"/> Lateral Breast		<input type="checkbox"/> Lateral Breast	
<input type="checkbox"/> Medial Breast		<input type="checkbox"/> Medial Breast	
<input type="checkbox"/> Areolar/Nipple Area		<input type="checkbox"/> Areolar/Nipple Area	
<input type="checkbox"/> Deep Against Chest Wall		<input type="checkbox"/> Deep Against Chest Wall	
<input type="checkbox"/> Scattered/Throughout Breast		<input type="checkbox"/> Scattered/Throughout Breast	
<input type="checkbox"/> Other, specify: _____		<input type="checkbox"/> Other, specify: _____	

14. Patient Notified of the Mammogram Findings? ☐ Date of Notification:

15. Cyst-Fine Needle Aspiration (FNA)

Done by: Date done:

☐ Mass resolved/fluid not bloody ☐ Fluid bloody

☐ Residual Mass

☐ Other, specify:

☐ Sent Fluid to Cytology

Results Obtained Stamped/Documented? Date:

Results Reviewed By FPCP Signed/Documented? Date:

Cytology Results:

☐ Insufficient/Hypocellular/Apocrine Cells ☐ Malignant
☐ Atypical cells ☐ Suspicious for malignancy ☐ Benign/Fibrocystic/Apocrine Cells
☐ Other, specify:

16. Patient Notified of the FNA Findings From Cytology? ☐ Date of Notification:

17. Solid Mass-Fine Needle Aspiration Biopsy (FNAB)

Done by: Date done:

☐ Specimen Submitted For Analysis

Results Obtained Stamped/Documented? Date:

Results Reviewed By FPCP Signed/Documented? Date:

Pathology Results:

☐ Insufficient/Hypocellular ☐ Benign/Fibrocystic ☐ Atypical cells
☐ Suspicious for malignancy ☐ Malignant
☐ Other, specify:

18. Patient Notified of the FNAB Findings From Path Report? ☐ Date of Notification:

19. Ultrasound Findings:

Ordered by: Date done:

Results Obtained Stamped/Documented? Date:

Results Reviewed By FPCP

Signed/Documented?

Date:

- ☐ Negative finding ☐ Simple cyst(s) ☐ Solid mass(es) or complex cyst(s)
☐ Other, specify: _____

20. Patient Notified of the Ultrasound Findings?

Date of Notification:

21. Image-Guided Biopsy/Open Biopsy Results: Date done:

Results Received

Stamped/Documented?

Date:

Results Reviewed By FPCP

Signed/Documented?

Date:

Open Biopsy Findings(check all that apply):

- | | |
|---|---|
| <input type="checkbox"/> Benign/No Evidence of Malignancy | <input type="checkbox"/> Ductal Carcinoma in situ |
| <input type="checkbox"/> Benign/Fibrocystic Changes | <input type="checkbox"/> Lobular Carcinoma in situ |
| <input type="checkbox"/> Benign/Fat Necrosis | <input type="checkbox"/> Atypical Hyperplasia |
| <input type="checkbox"/> Benign/Lipoma | <input type="checkbox"/> Invasive Ductal Carcinoma |
| <input type="checkbox"/> Benign/Fibroadenoma | <input type="checkbox"/> Invasive Lobular Carcinoma |
| <input type="checkbox"/> Other, specify: _____ | |

Go Back to Visit
Form

Go To
Followup Form

Form IV-Follow-up Entry

StudyID: [REDACTED]

Date of Visit: [REDACTED]

23. Recommended Follow-Up(s) (Check All That Apply)

☐ **Undocumented**

Follow-up for Normal CBE and Mammogram (or One of Them Undocumented):

<input type="checkbox"/> Routine Screening	<input type="checkbox"/> 12 Month CBE	<input type="checkbox"/> 12 Month Mammogram
<input type="checkbox"/> Following ACS Guidelines	<input type="checkbox"/> Following Other Guidelines	specify: [REDACTED]
Recommended by: [REDACTED]	Comments: [REDACTED]	

Follow-up for Specific Abnormalities:

Follow-up To Any Abnormalities:

Breast Mass/Asymetry Initial Approach:

- ☐ CBE at better phase cycle (3-10 days)
- ☐ Fine Needle Aspiration for Cyst

If Known Breast Cyst:

- ☐ Send Fluid to Cytology ☐ Reaspiration
- (How many) month CBE

If Known Solid Mass:

- ☐ Fine Needle Aspiration Biopsy
- ☐ Specimen Submitted for Analysis
- ☐ Repeat aspiration
- ☐ Clinical Followup Every 3 Months for 1 Year

For Nipple Discharge:

- ☐ Endocrine work-up

For Skin/Nipple Changes on Observation:

- ☐ 2 weeks antibiotics ☐ Skin Biopsy
- ☐ 2 weeks topical hydrocortisone

For Breast pain:

- ☐ Eliminate Caffeine
- ☐ Adjust Estrogen Dose
- ☐ Local Anesthetic Injection
- ☐ Primrose Oil, How Many Months?
- ☐ Reassurance and CBE within 3-6 months if pain persists
- ☐ Supportive Brassiere
- ☐ Over-the-counter Analgesics
- ☐ Danazol, Bromocriptine

For Occult Mammographic Abnormality:

- ☐ Radiologic Biopsy/Image-Guided Biopsy

Recommended by:

- ☐ Call if Problem Worsens

- ☐ Routine Screening

Recom. by: **Immediate Mammogram Workup:**

- ☐ Regular Mammogram
- ☐ Extra Mammogram Views
- ☐ Cone or Spot Compression
- ☐ Magnification Views

Recom. by: **Interval Followup:** (How many) month mammogra (How many) month CBERecom. by:

- ☐ Ultrasound

Recom. by:

- ☐ Surgical Referral

Recom. by:

- ☐ Undocumented

**Other Recommendations Or Comments
Concerning Abnormality(ies):****General Comments About This Visit:**

Assessment/Recommended Follow-up From Surgeon's Letter

1. Letter Written	Date:			
2. Letter Received	Stamped/Documented?		Date:	
3. Letter Reviewed by FPCP	Signed/Documented?		Date:	

Assessment

- ☐ Referral Diagnosis Not Confirmed
- ☐ Referral Diagnosis Confirmed
- ☐ Additional/New findings
- ☐ Further Tests Recommended/Done By Surgeon, check all that apply
 - ☐ Immediate Mammogra
 - ☐ Interval Mammogram, how long
 - ☐ Interval CBE, how long?
 - ☐ Ultrasound
 - ☐ FNA
 - ☐ FNAB
 - ☐ Radiological/Image Guided Biopsy
 - ☐ Open Biopsy
- Evidence of Malignancy?
- ☐ Previous Abnormality Resolved
- ☐ Current Abnormality Resolved
- ☐ Other Comments From Surgeon's Lette

Followup

- ☐ No Further Workup Required
- ☐ Followup In Primary Care Office
- ☐ Followup In Surgeon's Office

Go Back to
Form II

Go Back to
Form III

Add New
Visit

Add New
patient

Appendix 2

Kappa Calculation for Quality Control

To perform the quality control we chose the relevant fields in the database for which a kappa value could be calculated. The Kappa value is the ratio of the agreement actually observed minus the agreement expected by chance, divided by 1 (which corresponds to perfect agreement) minus the agreement expected by chance:

$$K = (P_A - P_C) / (1 - P_C)$$

Kappa statistics were derived using the SAS program. The simple kappa coefficient measures the agreement between the abstractors beyond what could be expected by chance.

Displayed below are three examples of the types of Kappa calculations performed on the data. These examples display the data collected, the SAS code used, and the output produced by SAS.

Examples of Kappa calculation:

1. For fields with numerical value entries:

The following table is the data entered by both the abstractor and quality control person for the question "Total numbers of visits within 15 months, including the most recent visit" (question #3 on Front End Form). In this case these numerical values were compared. In the table you will notice the discrepancy between the abstractor and quality control for patient number 4.

	Abstractor	Quality Control
Patient 1	6	6
Patient 2	2	2
Patient 3	2	2
Patient 4	5	6
Patient 5	3	3
Patient 6	4	4
Patient 7	6	6
Patient 8	9	9

After this table is made, the data is input into SAS for Kappa calculation. The Kappa results are the followings:

Kappa Statistics			
Statistic	Value	ASE	95% Confidence Bounds
Simple Kappa	0.8431	0.1430	0.5628 1.1234

Sample Size = 8

For fields with only 0 or 1 value, i.e. unchecked versus checked boxes respectively, in the ACCESS Database, a different method of Kappa calculation was used. An example of a scenario where this occurs is on form II-Visit Entry. In this section the abstractor is asked to record CBE documentation. One portion of the section is to indicate if the lymph node examination is documented. The following table was made comparing the abstractor versus quality control observations of whether during the CBE the doctor documented a lymph node examination. In this example “1” signify lymph node examination was documented and “0” means they it was not.

	Abstractor	Quality Control
Visit 1	0	1
Visit 2	0	0
Visit 3	0	0
Visit 4	0	0
Visit 5	0	0
Visit 6	0	0
Visit 7	1	1
Visit 8	1	1
Visit 9	0	0

```

Simple Kappa Coefficient
-----
Kappa                      0.7273

Sample Size = 9

```

There are some fields with Kappa value equaling 0%. For these situations included in parenthesis was the percent agreement. It has been documented and determined by our study group that in some situations the Kappa statistics is not the best way to represent the data and that in those situations the percent agreement is more appropriate.

The following table is the summary of bilateral mammogram documentation results for several patients comparing quality control to the abstractor. In this case “1” signifies mammogram documentation and “0” signifies no mammogram documentation. In this scenario the abstractor missed recording the mammogram documentation compared to the quality control for patient 4.

	Quality Control	Abstractor
Patient 1	1	1
Patient 2	1	1
Patient 3	1	1
Patient 4	1	0

The Kappa results are the followings:

Simple Kappa Coefficient

Kappa 0.0000

Sample Size = 4

On the other hand, the percent agreement is calculated to be:

$$(4 - 1) / 4 = 75\%$$

Table 1: Kappa Results From Form-I (General Information Form)

Abstractor ID	Eligibility Code	Date Most Recent Office Visit (Q2)	Total Number of Visits Within 15 Months (Q3)	Total Breast Care Related Encounter(s)
11	*	*	77%	88%
12	*	*	86%	*
21	64%	*	72%	58%
22	69%	*	89%	64%
31	*	*	84%	88%
32	*	*	85%	74%
41	60%	*	74%	70%
42	84%	86%	*	*
51	*	*	*	*
52	85%	*	70%	*
61	84%	*	88%	59%
62	*	89%	*	87%
71	83%	*	*	75%
81	*	86%	74%	*
82	*	*	*	84%
91	*	*	*	77%
92	86%	*	86%	67%

Note: "*" = 100% Kappa Result

Table 2: Kappa Results From Form-II (Visit Entry Form)

Abstractor ID	Type of Contact (Q6)	Symptom Lump R (Q9)	Symptom Lump L (Q9)	CBE Documentation			Abnormal Lump R (Q11)	Abnormal Lump L (Q11)
				Inspection (Q11)	Palpation (Q11)	Lymph Node Exam (Q11)		
11	*	*	*	*	*	78%	*	*
12	*	*	*	*	*	67%	0 (83)%	0 (83)%
21	*	*	*	*	*	*	*	*
22	*	*	*	62%	*	*	*	*
31	*	*	*	*	*	*	*	*
32	91%	*	0 (92)%	*	80%	*	0 (92)%	63%
41	88%	*	*	*	*	75%	*	*
42	*	*	*	*	*	*	*	63%
51	89%	*	*	*	*	*	*	*
52	*	*	*	*	*	*	*	*
61	*	*	*	71%	*	*	*	*
62	*	*	*	*	*	*	*	*
71	90%	*	*	77%	*	*	*	*
81	*	*	*	*	*	*	*	*
82	*	*	*	*	*	*	*	*
91	*	*	*	62%	*	49%	0 (91)%	0 (91)%
92	*	*	*	70%	*	70%	*	*

Note: “*” = 100% Kappa Result
() = percent agreement

Table 3: Kappa Results From Form-III (Test Result Entry Form)

Abs ID	Mammogram Findings											
	Cat I Right	Cat II Right	Cat III Right	Cat IV Right	Cat V Right	Cat VI Right	Cat I Left	Cat II Left	Cat III Left	Cat IV Left	Cat V Left	Cat VI Left
11	*	*	*	*	*	*	*	*	*	*	*	*
12	*	*	*	*	*	*	*	*	*	*	*	*
21	*	*	*	*	*	*	*	*	*	*	*	*
22	*	*	*	*	*	*	*	*	*	*	*	*
31	*	*	*	*	*	*	*	*	*	*	*	*
32	*	*	*	*	*	*	*	*	*	*	*	*
41	*	*	*	*	*	*	0 (80)%	*	*	*	*	*
42	0 (75)%	*	*	*	*	*	*	*	*	*	*	*
51	*	*	*	*	*	*	*	*	*	*	*	*
52	*	*	*	*	*	*	*	*	*	*	*	*
61	*	*	*	*	*	*	*	*	*	*	*	*
62	*	*	*	*	*	*	*	*	*	*	*	*
71	*	*	*	*	*	*	*	*	*	*	*	*
81	*	*	*	*	*	*	*	*	*	*	*	*
82	*	*	*	*	*	*	*	*	*	*	*	*
91	*	*	*	*	*	*	*	*	*	*	*	*
92	*	*	*	*	*	*	*	*	*	*	*	*

Note: Cat¹ = Category
 “*” = 100% Kappa Result
 () = percent agreement

Table 4: Kappa Results From Form-IV (Followup Form)

Abs ID	Undocu-mented	Routine Screening	12 month CBE	12 month mammo	Immediate Mammo	Extra Views	Interval Mammo	Interval CBE	Ultra-sound	Surgical Referral
11	83%	87%	*	*	*	*	*	*	*	0 (88)%
12	73%	78%	*	*	*	*	*	*	*	*
21	*	*	*	*	*	*	*	*	*	*
22	*	*	*	*	*	*	*	*	*	*
31	83%	*	0 (95) %	*	*	*	*	0 (95)%	*	*
32	*	*	*	*	*	*	*	*	*	*
41	66%	*	*	81%	*	*	*	*	*	*
42	*	*	*	*	*	*	*	*	63%	*
51	*	*	*	*	*	*	*	*	*	*
52	*	*	*	*	*	*	*	*	*	*
61	*	*	*	*	*	*	*	*	*	*
62	*	*	*	*	*	*	*	*	*	*
71	*	*	*	82%	*	*	*	*	*	*
81	*	*	*	*	*	*	*	*	*	*
82	*	*	*	*	*	*	*	*	*	*
91	*	*	*	*	*	*	*	*	*	*
92	*	*	*	*	*	*	*	*	*	*

Note: “*” = 100% Kappa Result
() = percent agreement

**Summary of the Grant
to Train Nurse Practitioners**

Improving the Quality of Breast Cancer Screening: Education for Nurse Practitioners

A Michigan Cancer Consortium (MCC) priority (Priorities: 1998-2002) is that by 2003, 80% of eligible women of Michigan will receive age appropriate, annual breast cancer screening (clinical breast exam and mammography), follow-up and appropriate treatment of abnormal findings. To that end, they recommend that educational plans be developed and deployed in order to educate health care providers. The breast cancer recommendation and plan from the MCC also includes the perspective that continuing education in cancer screening updates be required every 3 years for health care professionals. The model to be tested in this proposal, if successful, could be adopted to meet that goal. If we are to achieve the goals set out by the MCC, we must have educated professional practitioners who are fully cognizant of the guidelines. This project seeks to determine if an educational intervention for breast cancer screening originally designed for physicians can be adapted to educate nurse practitioners (NP's) in the performance of clinical breast exams (CBEs) and follow-up of abnormalities.

This program is designed to optimize skill acquisition for nurse practitioners in breast cancer screening. It includes didactic interventions for CBE and mammography with a skills component for clinical breast exam. To date, educational approaches for breast cancer screening have been directed at primary care physicians; now we propose to test the applicability of such a program for nurse practitioners. Research has not described either 1) nurse practitioner education for screening for breast cancer screening or 2) the impact of an educational intervention on the appropriateness of screening behavior by nurse practitioners.

We will implement a standard-based approach to breast cancer screening and follow-up skills that should lead to earlier diagnosis of breast cancer. We will seek to determine whether the curriculum used by physicians will be transferable to a curriculum for nurse practitioners and whether the skills will be maintained once taught. This project will be implemented in community based practice settings and health plans. If the curriculum proves effective, it would therefore be generalizable to any practice setting where NP's practice.

Nurse practitioners often work within low income and Medicaid clinics as well as within women's health clinics. The potential impact of having nurse practitioners educated to standard could be an important tool for delivery of healthcare to vulnerable populations.

Finally, the results of this project would begin to fill the gap in knowledge about CBE education for NP's as there is little information on clinical breast exam education for nurses and less on nurse practitioners. In addition, just the baseline Knowledge, Attitude and Behaviors (KAB) analysis for NP's will be a unique contribution.

The project will result in products that will make this program replicable in other venues where nurse practitioners practice:

- a Clinical Breast Cancer Screening curriculum that would be available for dissemination to health plans and/or practices or to be used by professional continuing education units for nurse practitioners;
- current breast cancer screening guidelines for practice;
- procedures to be used for testing sensitivity and specificity of breast models;
- guidelines for documentation of clinical breast exams;
- a survey for assessing knowledge, attitudes and behaviors around breast cancer screening adapted for nurse practitioners; and
- evaluation results on suitability of this training module for appropriate breast cancer screening for nurse practitioners.

As a result of this skills training of NP's, Michigan should experience increased rates of screening which will increase the number of women receiving timely screening and appropriate follow-up of results in order to meet the overall MCC goal. We expect that this will also be reflected in screening rates for vulnerable populations as well. A quality examination performed according to standards should lead to more accurate exams and prevent missed abnormalities as well, thereby improving another aspect of women's breast health in Michigan.

Project in collaboration with the Institute for Managed Care and College of Nursing, Department of Surgery at Michigan State University and the Michigan Department of Community Health - Cancer Control.

For information call Barbara Given, PhD., RN, FAAN, at 432-4326.

**SUBPROJECT: IMPROVING THE QUALITY OF BREAST CANCER SCREENING:
EDUCATION FOR NURSE PRACTITIONERS (GIVEN)**

Executive Summary The purpose of this project is to determine if an educational intervention directed toward knowledge with skill acquisition for breast cancer screening, originally designed for physicians, can be adapted to educate nurse practitioners (NP's) in their performance of clinical breast exams (CBE's). This project seeks to achieve Michigan Cancer Consortium's (MCC) goal of 80% of women receiving preventive screening with CBE's by the year 2003. We have created a curriculum that we are in the process of administering to NP's (125) from 5 communities around the state. The first sessions, three of which have been completed, are in progress. There is a four-month follow-up session to evaluate knowledge retention. The results of this project will begin to fill the gap in knowledge that currently exists on CBE education for nurses and NP's. In addition, just the baseline Knowledge, Attitude and Behaviors (KAB) analysis for NP's will be a unique contribution to the science. Finally, we hope to have a curriculum that can be used statewide, and perhaps broader, to develop and maintain CBE skills for NP's through continuing education. Partners are the Michigan Nurses Association (MNA), the Michigan Association of Health Plans (MAHP) and the College of Nursing at Michigan State University (MSU).

Background The goal of this project is to determine whether an existing physician intervention can be modified to optimize the sensitivity and specificity of clinical breast screening skills and then provided to NP's.

Project Objectives

1. Conduct an Educational Session (ES) designed to enhance the NP's knowledge of the anatomy and physiology of the breast, epidemiology of breast cancer, benefits

of screening, guidelines for both screening and for follow-up of abnormal findings. The knowledge acquired will be tested through a pre/post test approach.

2. To include a Clinical Skills (CS) Component to teach the technique of CBE and interpretation of findings from simulated silicone breast models.
3. To conduct an evaluation of the impact of the intervention at two times (immediately following the education and at four months) to see whether participating nurses maintain their CBE skills and can describe utilization.

Measures for the knowledge, attitude and behavior are calculated through the pre and post paper and pencil test and through simulation with the silicone breast models.

Currently, NP's conduct many of the clinical exams within Family Practice, Obstetrics and Gynecology and Women's Health Centers. This curriculum module, if accepted by the NP's and their skills improve, could be adapted and offered periodically statewide as a professional continuing education program focused on helping the NP's maintain their skills.

Target Audience The target audience is Michigan NP's who provide breast care as a part of their daily practice. A special mailing was sent to Breast Cancer and Cervical Program (BCCP) nurses and to members of MAHP. The challenge was in the heavy demand for limited spaces for attendance at the Essentials of Breast Care training session (Appendix G).

Expected Outcomes Expected outcomes are: 1) the program will be deemed appropriate, accepted and well attended by NP's; 2) we would expect to see improved knowledge, sensitivity and specificity in silicone model testing from the participants; and 3) we will have curriculum content, plan and materials that can be used by professional educators for developing skills of NP's. From the first site it appears as if the nurses care for women ages 21-60, low income (\$34,000 or under), 16% Medicaid and 31% no

insurance. Eight of twenty worked in organizations with no reminder systems for screening and no follow-up of no-shows; six had no follow-up system at all.

Planned deliverables

- Curriculum Delivery Plan
- Curriculum Content Materials
- Evaluation Materials/Pre- and Post-Test, Silicone Sheets for Testing
- Case Scenarios
- Data Analysis

Status Report *Objective: To Conduct the Educational Session of the Curriculum.*

The original Essentials of Breast Care program was prepared for primary care physician participants. The new curriculum content was modified slightly from that delivered to the physicians. Dr. Janet Osuch and Barbara Sparks, a nurse practitioner, reviewed, updated and revised the curriculum to cover anatomy and physiology, epidemiology, benefits of screening and guidelines. To specifically accommodate an Advanced Practice Nurse audience, the following modifications were made to the original curriculum:

- All references to physicians as the primary care givers were changed to reflect primary care as given by an Advanced Practice Nurse
- Discussions of mammographic abnormalities, significant clinical abnormalities and various clinical situations were modified to indicate referral more likely to be used by Advance Practice Nurses
- The time schedule and index were modified to reflect the adjusted content
- Appendices were adjusted to eliminate options primarily appropriate for physicians and indicate protocols more useful to Advance Practice Nurses

The curriculum content was completed by the end of December 2000, and it was delivered in Kalamazoo on January 11, 2001; Midland on February 1, 2001; and Howell on February 15, 2001. Sessions are planned for Traverse City on March 16, 2001, and

East Lansing on March 29, 2001. The clinical skills component was developed to be delivered through breast silicone model examination. There are 18 breast lesions that are scattered among 6 silicone breast models and these are used for the testing. The mechanism for determining the sensitivity and specificity for each NP are determined from lesions found or not found at the pre- and post-session. These measures will also be repeated at the four-month follow-up session.

The mailing to NP's was completed using the State of Licensing and Credentialing list of Nurse Practitioners, the nurses on the MSU College of Nursing Continuing Education list, MAHP's list of Medical Directors and also to a group of nurses who were a part of the State of Michigan BCCP program. Every slot for all five locations was immediately filled and a waiting list was established for each site. Consideration was given to expanding the number of NP's at each site to 30 but the participating faculty felt the number had to be limited, as initially planned, to maximize instruction. All applicants placed on the waiting list were contacted individually and all openings were filled from this list. A number of nurses called and requested we have additional sessions including two specific requests for sessions in the Upper Peninsula. Unfortunately, several nurses from state programs were unable to be accommodated.

So we could have later comparison, the participating faculty reviewed and modified the pre- and post-test and tried to keep it in the same format as the physician test.

The IRB at Michigan State University has been completed. Application to the MSU College of Nursing for CEU credit has also been completed. Data analysis plans are underway.

Evaluations of the first two sessions indicated an outstanding program (Appendix G). Preliminary review of the tests indicated that, although the general knowledge seemed high, there appeared to be improvement from pre- to post-testing. There was real variation in sensitivity and specificity with the silicone breast models, however, this will be an important area of focus from pre-to post-test to note improvement.

Summary of Accomplishments We are on time for the project. Overall, there was no change in plans or timeline and this program has been implemented as planned. We have accomplished the curriculum revisions, revised the course pack and implemented, with great success, the first two sessions in three out of five sites. There is enormous interest among nurses for this program—which is substantiated by the number of disappointed nurses who have been unable to attend.

Challenges, Solutions and Lessons Learned Many NP's were unable to attend a session and expressed extensive demand that session size and frequency be reconsidered. Faculty was asked to reconsider the size and frequency of sessions, but the demand on their time is such that we were unable to accommodate these requests.

Administrative Update The project staff is intact. Nancy Slone, RN, was added as a staff member to work with the faculty involved and assist with facilitating the on site sessions. Her biosketch can be found in Appendix F. Michigan Public Health Institute will be subcontracted to complete the data analysis

Support Data No direct services are provided.

Upcoming Activities We will complete the timeline as outlined.